



Lilly's Foundayo and lower-dose Zepbound helped people maintain weight loss after switching from higher doses of injectable incretin therapy in two late-phase trials

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In ATTAIN-MAINTAIN, participants who transitioned from a maximum tolerated dose (MTD) of Wegovy (semaglutide) to Foundayo maintained all but 0.9 kg of their previously achieved weight loss on average after one year

In ATTAIN-MAINTAIN and SURMOUNT-MAINTAIN, participants who switched from Zepbound MTD to Foundayo or reduced the dose of Zepbound to 5 mg, respectively, maintained all but 5.0 kg and 5.6 kg of their previous weight loss on average after one year

Participants in SURMOUNT-MAINTAIN who remained on Zepbound MTD for an additional year maintained all of their prior weight loss on average

INDIANAPOLIS, May 12, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced detailed results from two late-phase trials showing that people with obesity maintained their weight loss long term with either Foundayo or lower-dose Zepbound after switching from higher doses of injectable incretin therapy. The findings from SURMOUNT-MAINTAIN and ATTAIN-MAINTAIN, were presented at the 33rd European Congress on Obesity (ECO) and published in *The Lancet* and *Nature Medicine*, respectively.

"Weight regain remains one of the biggest challenges in obesity care, and is often the result of treatment interruptions that cause biology to work against patients, undoing the progress they've made," said Louis J. Aronne, M.D., FACP, DABOM, founder and Chair Emeritus of the American Board of Obesity Medicine, former president of The Obesity Society, Fellow of the American College of Physicians, world-renowned obesity specialist and Lilly consultant. "These medicines can be used for long-term maintenance today, and results from SURMOUNT-MAINTAIN and ATTAIN-MAINTAIN provide additional evidence of their potential when switching from higher doses of injectable incretin therapy."

In SURMOUNT-MAINTAIN, both Zepbound MTD and Zepbound 5 mg met the primary and all key secondary endpoints, demonstrating weight-loss maintenance after 60-weeks of initial treatment with Zepbound MTD.^{1,2} The primary endpoint was to demonstrate that continuation of Zepbound either at a reduced 5 mg dose or at MTD was superior to placebo in percent change in body weight at week 112. At week 112, participants continuing treatment with Zepbound MTD preserved all of their prior weight loss, while dose reduction to 5 mg maintained all but 5.6 kg on average.

SURMOUNT-MAINTAIN Weight Maintenance Results

	Zepbound MTD to Zepbound MTD	Zepbound MTD to Zepbound 5 mg
Avg. starting body weightⁱ	112.2 kg (247.4 lbs)	113.4 kg (250.0 lbs)
Avg. body weight after 60 weeks of Zepbound MTD^{ii,iii}	89.5 kg (197.3 lbs)	89.0 kg (196.2 lbs)
Avg. body weight at 52 weeks of maintenanceⁱⁱ	88.7 kg (195.6 lbs)	94.6 kg (208.6 lbs)

ⁱObserved mean based on efficacy estimand data set.

ⁱⁱMixed Model for Repeated Measures (MMRM) based on efficacy estimand data set.

ⁱⁱⁱTreatment was at maximum tolerated doses of Zepbound 10 mg or 15 mg.

ATTAIN-MAINTAIN demonstrated that switching to Foundayo also supported long-term weight maintenance, meeting the primary and all key secondary endpoints using both the efficacy estimand and treatment-regimen estimand.^{1,2} The primary endpoint was to demonstrate that Foundayo was superior to placebo in percent maintenance of body weight reduction, among SURMOUNT-5 participants who previously reached a body weight plateau. At week 52, participants who switched from Wegovy MTD to Foundayo maintained all but 0.9 kg of their previously achieved weight loss, while those who switched from Zepbound MTD to Foundayo maintained all but 5.0 kg.

ATTAIN-MAINTAIN Weight Maintenance Results

	Wegovy to Foundayo ^{iv}	Zepbound to Foundayo ^{iv}
Avg. starting body weightⁱ (at start of SURMOUNT-5)	113.5 kg (250.2 lbs)	115.8 kg (255.3 lbs)
Avg. weight at switch to oral^{i,ii} (at start of ATTAIN-MAINTAIN)	95.0 kg (209.4 lbs)	90.9 kg (200.4 lbs)
Avg. weight after 52 weeks of oral maintenanceⁱⁱⁱ (at end of ATTAIN-MAINTAIN)	95.9 kg (211.4 lbs)	95.9 kg (211.4 lbs)

ⁱObserved mean based on efficacy estimand data set.

ⁱⁱPost-hoc analysis.

ⁱⁱⁱMixed Model for Repeated Measures (MMRM) based on efficacy estimand data set.

^{iv}Treatment was at maximum tolerated doses of either 1.7 mg or 2.4 mg (Wegovy) or 10 mg or 15 mg (Zepbound).

"Obesity is a chronic disease requiring long-term treatment, and patients need more options they can stay on for the long run," said Kenneth Custer,

Ph.D., executive vice president and president, Lilly Cardiometabolic Health. "We are encouraged by the results of SURMOUNT-MAINTAIN and ATTAIN-MAINTAIN, which showed that both Zepbound and Foundayo, a once-daily oral GLP-1, provided durable weight-loss maintenance. Lilly is committed to providing people with multiple treatment options as they navigate their weight-loss journey."

Across both trials, Foundayo and Zepbound demonstrated safety profiles consistent with prior Phase 3 studies. In ATTAIN-MAINTAIN, the most common adverse events with Foundayo vs. placebo were nausea (18.8% vs. 4.1%), constipation (13.1% vs. 4.1%), vomiting (8.3% vs. 3.4%) or diarrhea (7.4% vs. 7.5%). Discontinuation rates due to adverse events for patients randomized to placebo or Foundayo were 4.8% (Foundayo from Wegovy), 7.6% (placebo from Wegovy), 7.2% (Foundayo from Zepbound) and 6.3% (placebo from Zepbound). In SURMOUNT-MAINTAIN, the most common adverse events during the maintenance period with Zepbound MTD and Zepbound 5 mg vs. placebo were diarrhea (7.2% and 4.9% vs. 1.1%), vomiting (6.5% and 0.7% vs. 0%) and nausea (5.8% and 4.2% vs. 2.2%). Discontinuation rates due to adverse events during the maintenance period with Zepbound MTD, Zepbound 5 mg and placebo were 0%, 0.7% and 0%, respectively.

About Zepbound

Zepbound (tirzepatide) is a once-weekly dual GIP (glucose-dependent insulinotropic polypeptide) receptor and GLP-1 (glucagon-like peptide-1) receptor agonist. Zepbound is a single molecule that activates the body's receptors for GIP and GLP-1, which are natural incretin hormones. Both GIP and GLP-1 receptors are found in areas of the human brain important for appetite regulation. Zepbound decreases calorie intake, and the effects are likely mediated by affecting appetite. Studies of tirzepatide in chronic kidney disease (CKD) and in morbidity/mortality in obesity (MMO) are ongoing.

Tirzepatide has been approved by the U.S. FDA as Mounjaro for adults with type 2 diabetes to improve glycemic control, and as Zepbound for adults with obesity, or some adults who are overweight and also have at least one weight-related medical problem, to lose weight and keep it off. Additionally, Zepbound is FDA-approved to treat adults with moderate-to-severe obstructive sleep apnea and obesity. Tirzepatide is also approved as Mounjaro in some countries outside the U.S. for adults with type 2 diabetes, obesity or those who are overweight who also have a weight-related comorbid condition. Both Mounjaro and Zepbound should be used in combination with diet and exercise.

About the SURMOUNT-MAINTAIN trial

SURMOUNT-MAINTAIN ([NCT06047548](#)) was a 112-week, Phase 3b, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of Zepbound (tirzepatide) versus placebo for maintenance of body weight reduction in adults with obesity or overweight with weight-related comorbidities, without type 2 diabetes. The study enrolled 441 participants, all of whom received open-label tirzepatide during a 60-week weight-loss period. Prior to randomization at week 60, all participants received open-label Zepbound at their maximum tolerated dose (10 mg or 15 mg), and those who achieved at least 5% weight loss and tolerated tirzepatide were then randomized in a 3:3:2 ratio to Zepbound 5 mg, Zepbound MTD, or placebo for a 52-week maintenance period.

The primary endpoint was to demonstrate that continuation of tirzepatide either at a reduced 5 mg dose or at MTD is superior to placebo in percent change in body weight at week 112. For the primary endpoint, those who stayed on Zepbound MTD lost 25.2 kg (22.4%), while those who reduced to the 5 mg dose of Zepbound lost 19.2 kg (17.0%) from baseline after 60 weeks of initial weight loss and 52 weeks of maintenance.

About Foundayo³

Foundayo (orforglipron) is FDA-approved for adults with obesity, or some adults with overweight who also have weight-related medical problems to reduce excess body weight and maintain weight reduction long term, alongside a reduced-calorie diet and increased physical activity. Foundayo is a once-daily small molecule (non-peptide) oral glucagon-like peptide-1 receptor agonist that can be taken any time of the day without restrictions on food and water intake. Orforglipron was discovered by Chugai Pharmaceutical Co., Ltd. and licensed by Lilly in 2018. In addition to chronic weight management, orforglipron is being studied as a potential treatment for type 2 diabetes, obstructive sleep apnea, osteoarthritis knee pain, hypertension, peripheral artery disease and stress urinary incontinence.

About ATTAIN-MAINTAIN trial and ATTAIN clinical trial program

ATTAIN-MAINTAIN ([NCT06584916](#)) consisted of two 52-week, Phase 3b, randomized, double-blind, placebo-controlled cohorts comparing the efficacy and safety of once-daily Foundayo (orforglipron) for investigational use versus placebo for maintenance of body weight reduction in adults with obesity or overweight with weight-related comorbidities who previously completed the SURMOUNT-5 head-to-head trial. The ATTAIN-MAINTAIN trial randomized 376 participants across the U.S. in a 3:2 ratio to receive either Foundayo MTD 14.5 mg or 17.2 mg or placebo, as an adjunct to healthy diet and physical activity. This trial was conducted using an investigational formulation of Foundayo at dosages equivalent to Foundayo tablets.

The primary endpoint was to demonstrate that Foundayo is superior to placebo in the percent maintenance of body weight reduction in participants who achieved weight plateau with either Zepbound or Wegovy in the [SURMOUNT-5 trial](#). For the primary endpoint, participants who switched from Wegovy or Zepbound to Foundayo, respectively, maintained 82.4% and 78.0% of their previously achieved weight loss after one year. Weight plateau was defined as <5% body weight change between weeks 60 and 72 in SURMOUNT-5. In ATTAIN-MAINTAIN, participants started at 9 mg of once-daily, oral Foundayo (or matching placebo), with the dose increased every four weeks until MTD was reached. Starting at week 24, all participants who regained 50% or more of their body weight loss from SURMOUNT-5 were treated with rescue Foundayo up to MTD therapy in this novel, patient-centric approach to clinical trial design.

Endnotes and References

1. The efficacy estimand represents efficacy had all randomized participants remained on study intervention (with possible dose interruptions and/or dose modifications) for 52 weeks after randomization without initiating prohibited weight management treatments, and assuming participants who took rescue Zepbound or rescue Foundayo would not have received any additional improvement from their randomized study treatment.
2. The modified treatment-regimen estimand represents the estimated average treatment effect regardless of adherence to study intervention or initiation of prohibited weight management treatments or procedures, and assuming participants who took rescue Zepbound or Foundayo would not have received any additional improvement from their randomized study treatment.
3. Ma X, Liu R, Pratt EJ, Benson CT, Bhattachar SN, Sloop KW. Effect of Food Consumption on the Pharmacokinetics, Safety, and Tolerability of Once-Daily Orally Administered Orforglipron (LY3502970), a Non-peptide GLP-1 Receptor

INDICATION AND SAFETY SUMMARY WITH WARNINGS

Foundayo™ (fown-DAY-oh) is a prescription medicine used with a reduced-calorie diet and increased physical activity to help adults with obesity, or some adults with overweight who also have weight-related medical problems, to lose excess body weight and keep the weight off.

- Foundayo should not be used with other GLP-1 receptor agonist medicines.
- It is not known if Foundayo is safe and effective for use in children.

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

Foundayo may cause serious side effects, including:

Inflammation of the pancreas (pancreatitis). Stop taking Foundayo 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 nausea or vomiting. Sometimes you may feel the pain from your abdomen to your back.

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

Dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Foundayo with medicines that can cause low blood sugar, such as an insulin or sulfonylurea. **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, mood changes, hunger, weakness, or feeling jittery.

Serious allergic reactions. Stop using Foundayo 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, or very rapid heartbeat.

Changes in vision in patients with type 2 diabetes. Tell your healthcare provider if you have changes in vision during treatment with Foundayo.

Gallbladder problems. Gallbladder problems have happened in some people who use Foundayo. 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), or clay-colored stools.

Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Foundayo may increase the chance of food getting into your lungs during surgery or other procedures. Tell your healthcare providers that you are taking Foundayo before you are scheduled to have surgery or other procedures.

Common side effects

The most common side effects of Foundayo include nausea, constipation, diarrhea, vomiting, indigestion, stomach (abdominal) pain, headache, swollen belly, feeling tired, belching, heartburn, gas, and hair loss. These are not all the possible side effects of Foundayo. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

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

Before taking Foundayo

- **Tell your healthcare provider about all the medicines you take.** Foundayo may affect the way some medicines work, and some medicines may affect the way Foundayo works.
- **Pregnancy Exposure Registry:** There will be a pregnancy exposure registry for women who have taken Foundayo during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry, or you may contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).
- **If you take birth control pills by mouth, talk to your healthcare provider before you take Foundayo. Birth control pills may not work as well while taking Foundayo.** Your healthcare provider may recommend another type of birth control for 30 days after starting Foundayo and for 30 days after each dose increase of Foundayo.
- **Talk to your healthcare provider about low blood sugar and how to manage it.** Tell your healthcare provider if you are taking medicines to treat diabetes including an insulin or sulfonylurea.

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 liver, severe problems with

your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?

- ☐ Do you have a history of diabetic retinopathy?
- ☐ Are you scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)?
- ☐ Are you pregnant or plan to become pregnant? Foundayo may harm your unborn baby.
- ☐ Are you breastfeeding or plan to breastfeed? Breastfeeding is not recommended during treatment with Foundayo.
- ☐ Do you take any other prescriptions or over-the-counter medicines, vitamins, or herbal supplements?

How to take

- Take Foundayo exactly as your healthcare provider tells you to.
- Use Foundayo with a reduced-calorie diet and increased physical activity.
- Take Foundayo by mouth 1 time each day, with or without food.
- Swallow tablets whole. Do not break, crush, or chew the tablet.
- If you miss a dose, take it as soon as possible. **Do not take 2 doses of Foundayo in the same day.**
- **Do not take more than 1 tablet per day.**
- If you miss taking Foundayo for 7 or more days in a row, call your healthcare provider to talk about how to restart your treatment.
- If you take too much Foundayo, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Learn more

Foundayo is a prescription medicine available in 0.8 mg, 2.5 mg, 5.5 mg, 9 mg, 14.5 mg, or 17.2 mg oral tablets. For more information, call 1-800-545-5979 or go to foundayo.lilly.com.

INDICATIONS AND SAFETY SUMMARY WITH WARNINGS

Zepbound® (ZEHP-bownd) is an injectable prescription medicine used with a reduced-calorie diet and increased physical activity to help adults with:

- obesity, or some adults with overweight who also have weight-related medical problems, to lose excess body weight and keep the weight off.
- moderate-to-severe obstructive sleep apnea (OSA) and obesity to improve their OSA.

Zepbound contains tirzepatide and should not be used with other tirzepatide-containing products or any GLP-1 receptor agonist medicines. It is not known if Zepbound is safe and effective for use in children.

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

KwikPen®: Do not share your KwikPen with other people, even if the pen needle has been changed. You may give other people a serious infection or get a serious infection from them.

Zepbound may cause serious side effects, including:

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

Dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.

Gallbladder problems. Gallbladder problems have happened in some people who use Zepbound. 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), or clay-colored stools.

Inflammation of the pancreas (pancreatitis). Stop using Zepbound 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 nausea or vomiting. You may feel the pain from your abdomen to your back.

Serious allergic reactions. Stop using Zepbound 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, or very rapid heartbeat.

Low blood sugar (hypoglycemia). Your risk for getting low blood sugar may be higher if you use Zepbound with medicines 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, mood changes, hunger, weakness or feeling jittery.

Changes in vision in patients with type 2 diabetes. Tell your healthcare provider if you have changes in vision during treatment with Zepbound.

Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Zepbound may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking Zepbound before you are scheduled to have surgery or other procedures.

Common side effects

The most common side effects of Zepbound include nausea, diarrhea, vomiting, constipation, stomach(abdominal) pain, indigestion, injection site reactions, feeling tired, allergic reactions, belching, hair loss, and heartburn. These are not all the possible side effects of Zepbound. Talk to your healthcare provider about any side effect that bothers you or doesn't go away.

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

Before using Zepbound

- **Your healthcare provider should show you how to use Zepbound before you use it for the first time.**
- **Talk to your healthcare provider about low blood sugar and how to manage it. Tell your healthcare provider if you are taking medicines to treat diabetes including an insulin or sulfonylurea.**
- **If you take birth control pills by mouth, talk to your healthcare provider before you use Zepbound. Birth control pills may not work as well while using Zepbound.** Your healthcare provider may recommend another type of birth control for 4 weeks after you start Zepbound and for 4 weeks after each increase in your dose of Zepbound.

Review these questions with your healthcare provider:

- ☐ Do you have other medical conditions, including problems with your pancreas, or severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems digesting food?
- ☐ Do you take diabetes medicines, such as insulin or sulfonylureas?
- ☐ Do you have a history of diabetic retinopathy?
- ☐ Are you scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)?
- ☐ Do you take any other prescription medicines or over-the-counter drugs, vitamins, or herbal supplements?
- ☐ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? Zepbound may harm your unborn baby. Tell your healthcare provider if you become pregnant while using Zepbound. Zepbound may pass into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while using Zepbound.

• **Pregnancy Exposure Registry:** There will be a pregnancy exposure registry for women who have taken Zepbound during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your healthcare provider about how you can take part in this registry, or you may contact Lilly at 1-800-LillyRx (1-800-545-5979).

How to take

- Read the Instructions for Use that come with Zepbound.
- Use Zepbound exactly as your healthcare provider says.
- Use Zepbound with a reduced-calorie diet and increased physical activity.
- Inject Zepbound under the skin (subcutaneously) of your stomach (abdomen), thigh, or have another person inject in the back of the upper arm. **Do not** inject ZEPBOUND into a muscle (intramuscularly) or vein (intravenously).
- **Use Zepbound 1 time each week, at any time of the day.**
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.

If you take too much Zepbound, call your healthcare provider, call the Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Zepbound is approved as a 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, and 15 mg injection.

Learn more

Zepbound is a prescription medicine. For more information, call 1-800-LillyRx (1-800-545-5979) or go to www.zepbound.lilly.com.

This summary provides basic information about Zepbound but 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 Zepbound and how to take it. Your healthcare provider is the best person to help you decide if Zepbound is right for you.

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MOUNJARO 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 is safe and effective for use in children.

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 nausea or vomiting. Sometimes 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.

Dehydration leading to kidney problems. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration), which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.

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.

Food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation). Mounjaro may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking Mounjaro before you are scheduled to have surgery or other procedures.

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 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 scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation)?
- ☐ Are you pregnant, plan to become pregnant, breastfeeding, or plan to breastfeed? It is not known if Mounjaro will harm your unborn baby. Mounjaro may 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.
- A caregiver may give you Mounjaro injections, or you may self-inject if a healthcare provider determines that it is appropriate.
- Inject Mounjaro under the skin (subcutaneously) of your stomach (abdomen), thigh, or another person should inject in the back of the upper arm. **Do not** inject Mounjaro into a muscle (intramuscularly) or vein (intravenously).
- **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 Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Learn more

Mounjaro is a prescription medicine available as a pre-filled single-dose pen in 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL injection. For more information, call 1-800-LillyRX (800-545-5979) or go to www.mounjaro.lilly.com.

This summary provides basic information about Mounjaro but 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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About Lilly

Lilly is a medicine company turning science into healing to make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help tens of millions of people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges: redefining diabetes care; treating obesity and curtailing its most devastating long-term effects; advancing the fight against Alzheimer's disease; providing solutions to some of the most debilitating immune system disorders; and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/news, or follow us on [Facebook](https://www.facebook.com/Lilly), [Instagram](https://www.instagram.com/Lilly), and [LinkedIn](https://www.linkedin.com/company/lilly). P-LLY

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Zepbound (tirzepatide) and Foundayo (orforglipron) as treatments for adults with obesity, or adults with overweight with weight-related medical problems and reflects Lilly's current beliefs and expectations. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of drug research, development, and commercialization. Among other things, there is no guarantee that planned or ongoing studies will be completed as planned or that future study results will be consistent with study results to date. For further discussion of these and other risks and uncertainties that could cause actual results to differ from Lilly's expectations, see Lilly's Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

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