Lilly's Mounjaro (tirzepatide), a GIP/GLP-1 dual agonist, demonstrated cardiovascular protection in landmark head-to-head trial, reinforcing its benefit in patients with type 2 diabetes and heart disease

July 31, 2025

Mounjaro met the primary objective of non-inferiority vs. Trulicity with an 8% lower rate of MACE-3 events, while delivering greater reductions in A1C and weight

In the trial, Mounjaro was associated with a 16% lower rate of all-cause death compared to Trulicity, suggesting more comprehensive health benefits

Results from the largest and longest Mounjaro trial to date reaffirm its established safety and tolerability profile

INDIANAPOLIS, July 31, 2025 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced topline results from SURPASS-CVOT, a first-of-its-kind head-to-head Phase 3 cardiovascular outcomes trial comparing two incretin therapies in adults with type 2 diabetes and established atherosclerotic cardiovascular disease. Mounjaro (tirzepatide), a GIP/GLP-1 dual receptor agonist, was compared to Trulicity (dulaglutide), a GLP-1 receptor agonist that showed a definitive cardiovascular benefit in the REWIND study. In SURPASS-CVOT, Mounjaro achieved the primary objective by demonstrating a non-inferior rate of major adverse cardiovascular events (MACE-3), including cardiovascular death, heart attack or stroke vs. Trulicity. In addition, while not controlled for multiplicity-adjusted type-1 error, Mounjaro showed improvements on key measures of A1C, weight, renal function and all-cause mortality. The trial, which enrolled more than 13,000 participants across 30 countries and lasted more than four and a half years, is the largest and longest study of tirzepatide to date.

"Cardiovascular disease remains the leading cause of death among people living with type 2 diabetes," said Kenneth Custer, Ph.D., executive vice president and president, Lilly Cardiometabolic Health. "The SURPASS-CVOT results show that Mounjaro preserved the cardioprotective benefit of Trulicity, a GLP-1 receptor agonist, while providing additional benefits, including greater kidney protection and a reduced overall risk of death. These findings strengthen the case for Mounjaro as a potential front-line treatment for people with type 2 diabetes and cardiovascular disease."

In the trial, the risk of cardiovascular death, heart attack, or stroke was 8% lower for Mounjaro vs. Trulicity (hazard ratio: 0.92; 95.3% CI: 0.83 to 1.01), meeting the prespecified criteria for non-inferiority (upper limit of 95.3% CI of the hazard ratio < 1.05).[1,2] Mounjaro showed consistent results across all three components of the MACE-3 composite endpoint. The rate of all-cause mortality was 16% lower for Mounjaro vs. Trulicity (hazard ratio: 0.84; 95.0% CI: 0.75 to 0.94).[1,3]

A pre-specified indirect comparison analysis of matched patient-level data from the REWIND and SURPASS-CVOT studies found that Mounjaro reduced the risk of MACE-3 by 28% (hazard ratio: 0.72; 95.0% CI: 0.55 to 0.94) and all-cause mortality by 39% (hazard ratio: 0.61; 95.0% CI: 0.45 to 0.82) compared to a putative placebo.[3,4] In another key pre-specified analysis of participants with high or very-high risk of chronic kidney disease, Mounjaro slowed eGFR decline by 3.54 mL/min/1.73 m^2 at 36 months vs. Trulicity (95.0% CI: 2.57 to 4.50).[3,5,6]

Primary and Select Secondary Endpoints:

	Mounjaro (tirzepatide)	**Trulicity (dulaglutide)**
Primary Endpoint		
Time-to-first occurrence of MACE-3[i]	Hazard ratio = 0.92 95.3%[ii] CI: 0.83 to 1.01[iii] p = 0.086	
Secondary Endpoints		
Time to all-cause death[i]	Hazard ratio = 0.84 95.0% CI: 0.75 to 0.94 p = 0.002[iv]	
Change in eGFR in chronic kidney disease population from mean baseline of 53.4 mL/min/1.73 m^2 at 36 months[v]	-4.97 mL/min/1.73 m^2	-8.51 mL/min/1.73 m^2
	Estimated treatment difference: 3.54 mL/min/1.73 m^2 (95.0% CI: 2.57 to 4.50) p < 0.001[iv]	
A1C reduction from mean baseline of 8.39% at 36 months[v,vi]	1.73 %	0.90 %
	Estimated treatment difference: -0.83% (95.0% CI: -0.88 to -0.78) p < 0.001[iv]	
Change from mean baseline of 92.6 kg (204.15 lbs) in body weight at 36 months[v,vi]	-12.06% (-11.43 kg / -25.20 lbs)	-4.95% (-4.65 kg / -10.25 lbs)
	Estimated treatment difference: -7.1% (95.0% CI: -7.4 to -6.8) p < 0.001[iv]	

[i] *Time-to-first event analysis using Cox proportional hazard model.*

[ii] *95.3% CI reported due to type 1 error rate adjusted for efficacy interim analysis.*

[iii] *Boundary for non-inferiority statistical significance < 1.05.*

[iv] *Not controlled for multiplicity-adjusted type 1 error rate.*

[v] *Baseline values represent the overall mean combining the Mounjaro and Trulicity groups.*

[vi] *Analysis of change from baseline to 36 months using ANCOVA model with multiple imputation of missing data.*

In the trial, Mounjaro also led to greater improvements in A1C, weight and cardiovascular biomarkers, including lipids and systolic blood pressure, compared to Trulicity.[3] The safety and tolerability of Mounjaro and Trulicity were generally consistent with their established profiles. The most commonly reported adverse events in SURPASS-CVOT for both Mounjaro and Trulicity were gastrointestinal-related, generally mild-to-moderate in severity, and mostly resolved after dose escalation was complete. During the trial, 13.3% of participants taking Mounjaro discontinued treatment due to adverse events, compared to 10.2% of participants taking Trulicity.[7]

Detailed results for SURPASS-CVOT will be presented at the European Association for the Study of Diabetes (EASD) Annual Meeting 2025 in September and published in a peer-reviewed journal. Lilly plans to submit these data to global regulatory authorities by the end of this year.

About SURPASS-CVOT

SURPASS-CVOT (Cardiovascular Outcomes Trial; NCT04255433) was an event-driven, randomized, double-blind, parallel group Phase 3 trial evaluating the efficacy and safety of Mounjaro (tirzepatide) compared with Trulicity (dulaglutide) in adults with type 2 diabetes and established atherosclerotic cardiovascular disease, which lasted approximately five years (with a median follow-up of four years). In the trial, 13,299 participants were randomized 1:1 across 640 sites in 30 countries to receive the maximum tolerated dose (MTD) of Mounjaro (5 mg, 10 mg or 15 mg) or Trulicity (1.5 mg) administered subcutaneously once weekly. The primary objective of the trial was to demonstrate that Mounjaro provided a non-inferior reduction in the risk of major adverse cardiovascular events (MACE-3)—a composite of cardiovascular death, heart attack or stroke—compared tc Trulicity. SURPASS-CVOT utilized MTD of 5 mg, 10 mg or 15 mg once weekly. The starting dose of 2.5 mg Mounjaro was increased by 2.5 mg every four weeks until MTD was achieved. Participants who tolerated 15 mg continued on 15 mg as their MTD. Participants who tolerated 10 mg but did not tolerate 15 mg continued on 10 mg as their MTD, and participants who tolerated 5 mg but did not tolerate 10 mg continued on 5 mg as their MTD.

About REWIND (2019)

REWIND (NCT01394952) was a multicenter, randomized, double-blind, placebo-controlled trial, published in 2019, designed to assess the effect of Trulicity (1.5 mg) compared to placebo in adults with type 2 diabetes with and without established cardiovascular disease. The primary cardiovascular outcome was the first occurrence of MACE-3. Secondary outcomes include each component of the primary composite cardiovascular outcome, a composite clinical microvascular outcome comprising retinal or renal disease, hospitalization for unstable angina, heart failure requiring hospitalization or an urgent heart failure visit, and all-cause mortality. In the trial, 9,901 participants from 24 countries had a mean duration of diabetes of 10.5 years and a median baseline A1C of 7.2%.

About tirzepatide

Tirzepatide is a once-weekly dual GIP (glucose-dependent insulinotropic polypeptide) receptor and GLP-1 (glucagon-like peptide-1) receptor agonist. Tirzepatide 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. Tirzepatide 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.

Endnotes and References

1. Time-to-first event analysis using Cox proportional hazard model.
2. 95.3% CI reported due to type 1 error rate adjusted for efficacy interim analysis.
3. Not controlled for multiplicity-adjusted type 1 error rate.
4. Hazard ratio estimates related to indirect comparison used Cox proportional hazard model adjusted with stabilized inverse-probability weight based on probability of a patient belonging to SURPASS-CVOT given baseline covariates.
5. Analysis of change from baseline to 36 months using ANCOVA model with multiple imputation of missing data.
6. Subgroup defined as patients with high or very-high risk chronic kidney disease, per KDIGO 2025 guidelines. Kidney function was assessed by change in eGFR using the CKD-EPI Creatinine-Cystatin 2021 equation over 36 months.
7. Percentage calculated based on modified intent-to-treat population.

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 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.

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.

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 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.
- Inject Mounjaro under the skin (subcutaneously) of your stomach (abdomen), thigh, or 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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INDICATIONS AND SAFETY SUMMARY WITH WARNINGS
Zepbound (ZEHP-bownd) is an injectable prescription medicine that may 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.

It should be used with a reduced-calorie diet and increased physical activity.

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.

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.

Kidney problems (kidney failure). 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.

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 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.

Depression or thoughts of suicide. You should pay attention to changes in your mood, behaviors, feelings or thoughts. Call your healthcare provider right away if you have any mental changes that are new, worse, or worry you.

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.**
- **Tell your healthcare provider if you are taking medicines to treat diabetes including an insulin or sulfonylurea which could increase your risk of low blood sugar. Talk to your healthcare provider about low blood sugar levels and how to manage them.**
- **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 kidneys, 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. It is not known if Zepbound passes 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.
- Zepbound is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **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, seek medical advice promptly, or contact a Poison Center expert right away at 1-800-222-1222.

Zepbound injection is approved as a 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg per 0.5 mL in single-dose pen or single-dose vial.

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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INDICATIONS AND SAFETY SUMMARY WITH WARNINGS

Trulicity® (Trū-li-si-tee) is for adults and children 10 years of age and older with type 2 diabetes used along with diet and exercise to improve blood sugar (glucose). [Trulicity is also used in adults with type 2 diabetes to reduce the risk of major cardiovascular events (problems having to do with the heart and blood vessels) such as death, heart attack, or stroke in people who have heart disease or multiple cardiovascular risk factors.]

- It is not known if Trulicity is safe and effective to lower blood sugar (glucose) in children under 10 years of age.
- Trulicity is given through an injection (needle). You take it once a week by injecting it under the skin of your stomach, thigh, or upper arm.

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

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

Ask your healthcare provider how to recognize the serious side effects below and what to do if you think you have one:

Inflamed pancreas (pancreatitis). Stop using Trulicity and call your healthcare provider right away if you have severe pain in your stomach area (abdomen), with or without vomiting, that will not go away. 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 TRULICITY 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, confusion or drowsiness, headache, blurred vision, slurred speech, fast heartbeat, sweating, hunger, shakiness, feeling jittery, weakness, anxiety, irritability, or mood changes.

Serious allergic reactions. Stop using Trulicity and get medical help right away if you have any symptoms of a serious allergic reaction which may include swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting, or feeling dizzy, or 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 Trulicity. 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 your eyesight (vision) during treatment with Trulicity.

Gallbladder problems. Gallbladder problems have happened in some people who take Trulicity. 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), clay-colored stools.

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

Common side effects

The most common side effects of Trulicity include nausea, diarrhea, vomiting, abdominal pain and decreased appetite, indigestion, and fatigue.

These are not all the possible side effects of Trulicity.

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

- **Your healthcare provider should show you how to use Trulicity before you use it for the first time.**
- **Before you use Trulicity, talk to your healthcare provider about low blood sugar and how to manage it.**

Review these questions with your healthcare provider:

□ Do you have other medical conditions, including problems with your pancreas, kidneys, liver, or stomach, or have a history of diabetic retinopathy (vision problems related to diabetes)?
□ Do you take other diabetes medicines, such as insulin or sulfonylureas?
□ 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 or breastfeeding or plan to breastfeed?
□ 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 Trulicity.
- Use Trulicity exactly as your healthcare provider says.
- Inject Trulicity under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. Do not inject Trulicity into a muscle (intramuscularly) or vein (intravenously).
- Do not share your Trulicity pen, syringe, or needles with another person.
- Do not give Trulicity to other people.
- If you take too much Trulicity, call your healthcare provider or Poison Helpline at 1-800-222-1222 or go to the nearest hospital emergency room right away.

Learn more

Trulicity is a prescription medicine available as a pre-filled single-dose pen in 0.75 mg,1.5 mg, 3 mg, or 4.5 mg per 0.5 mL injection. For more information, call 1-800-LillyRx (800-545-5979) or go to **www.trulicity.lilly.com.**

This summary provides basic information about Trulicity 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 Trulicity and how to take it. Your healthcare provider is the best person to help you decide if Trulicity 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, Instagram and LinkedIn. 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), including statements about the efficacy and safety of Mounjaro (tirzepatide) as a potential treatment for adults with type 2 diabetes, and reflects Lilly's current belief 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 can be no guarantee that future study results will be consistent with the results to date, that Mounjaro will receive additional regulatory approvals, or that Lilly will execute its strategy as planned. For further discussion of these and other risks and uncertainties, see Lilly's most recent 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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