



Lilly's Once-Weekly Trulicity® (dulaglutide) Label Updated to Include Data Showing Benefits for Adults with Type 2 Diabetes and Chronic Kidney Disease

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INDIANAPOLIS, July 19, 2018 /PRNewswire/ -- The U.S. label for Eli Lilly and Company's (NYSE: LLY) once-weekly Trulicity® (dulaglutide) is updated to show the medicine's safety and efficacy in people with type 2 diabetes who have moderate to severe chronic kidney disease (CKD). The label now includes data from the AWARD-7 clinical trial, which showed that people treated with Trulicity 1.5 mg or 0.75 mg in combination with mealtime insulin lispro achieved similar glycemic control with weight loss, compared to those treated with traditional basal-bolus insulin.¹ Trulicity is a once-weekly glucagon-like peptide-1 (GLP-1) receptor agonist (RA) injectable prescription medicine to improve blood sugar (glucose) in adults with type 2 diabetes. It should be used along with diet and exercise.

The Centers for Disease Control and Prevention estimate that about a third of people with diabetes may develop kidney disease.² People with type 2 diabetes and moderate to severe CKD tend to have higher blood sugar levels and more advanced diabetes.³ Treating this population can be challenging because many diabetes treatments are either contraindicated or require dose adjustments.⁴ AWARD-7 was the largest study of its kind for a GLP-1 RA, exclusively enrolling people with type 2 diabetes and late-stage CKD. The positive study results were published online first in *The Lancet Diabetes & Endocrinology* on June 14, 2018.

AWARD-7 results showed that at 26 and 52 weeks, both Trulicity doses plus mealtime insulin lispro provided similar glycemic control to insulin glargine plus mealtime insulin lispro. All treatment groups had between a 1 percent and 1.2 percent reduction in A1C from baseline at both endpoints.¹ At the 26-week primary endpoint, up to 78 percent of all study participants across each treatment group reached target A1C levels of less than 8 percent; at 52 weeks, approximately 70 percent achieved those results.

In addition, people in the study treated with Trulicity lost weight (Trulicity 1.5 mg: -2.8 kg, -2.7 kg, 26 and 52 weeks, respectively; Trulicity 0.75 mg: -2.0 kg, -1.7 kg, 26 and 52 weeks, respectively), while people taking insulin glargine gained weight (+1.1 kg, +1.6 kg, 26 and 52 weeks, respectively).

"AWARD-7 showed that the combination of once-weekly Trulicity and mealtime insulin improved A1C as effectively as commonly used titrated basal-bolus insulin treatment, with the added benefit of weight loss," said Brad Woodward, M.D., senior medical director, Lilly Diabetes. "The addition of these data to our label reinforces Trulicity's powerful efficacy. Combined with its simple, once-weekly injection experience, we believe Trulicity stands out as a best-in-class first injection option to help people with type 2 diabetes achieve their blood sugar goals."

Indication and Limitations of Use for Trulicity®

Trulicity is a once-weekly injectable prescription medicine to improve blood sugar (glucose) in adults with type 2 diabetes mellitus. It should be used along with diet and exercise. Trulicity is not recommended as the first medication to treat diabetes. It has not been studied in people who have had inflammation of the pancreas (pancreatitis). Trulicity should not be used by people with type 1 diabetes, people with diabetic ketoacidosis, or people with a history of severe gastrointestinal (GI) disease. It is not a substitute for insulin. It has not been studied in children under 18 years of age.

Important Safety Information for Trulicity®

Patients should tell their healthcare provider if they get a lump or swelling in their neck, have hoarseness, trouble swallowing, or shortness of breath while taking Trulicity. These may be symptoms of thyroid cancer. In studies with rats or mice, Trulicity and medicines that work like Trulicity caused thyroid tumors, including thyroid cancer. It is not known if Trulicity will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people. Patients should not take Trulicity if they or any of their family members have ever had MTC or if they have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Patients should not take Trulicity if they have had an allergic reaction to dulaglutide or any of the other ingredients in Trulicity.

Trulicity should not be used in children under 18 years of age.

Trulicity may cause serious side effects, including:

- **Inflammation of the pancreas (pancreatitis).** If a patient has pain in their stomach area (abdomen) that is severe and will not go away, they should stop taking Trulicity and call their healthcare provider right away. The pain may happen with or without vomiting. It may be felt going from the abdomen through to the back.
- **Low blood sugar (hypoglycemia).** If patients are using another medicine that can cause low blood sugar (such as insulin or a sulfonyleurea) while taking Trulicity, their risk for getting low blood sugar (hypoglycemia) may be higher. Signs and symptoms of low blood sugar may include dizziness, blurred vision, anxiety, irritability, mood changes, sweating, slurred speech, hunger, confusion or drowsiness, shakiness, weakness, headache, fast heartbeat, or feeling jittery. Patients should

talk to their healthcare provider about low blood sugar and how to manage it.

- **Serious allergic reactions.** Patients should stop taking Trulicity and get medical help right away if they have symptoms of a serious allergic reaction including: swelling of the face, lips, tongue or throat; problems breathing or swallowing; severe rash or itching; fainting or feeling dizzy; or very rapid heartbeat.
- **Kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration). This may cause kidney problems to get worse.
- **Severe stomach problems.** Trulicity may cause stomach problems, which could be severe.

Patients should tell their healthcare provider if they:

- have or have had problems with their pancreas, kidneys, or liver.
- have severe problems with their stomach, such as slowed emptying of the stomach (gastroparesis) or problems with digesting food.
- have any other medical conditions.
- are pregnant or plan to become pregnant, or if they become pregnant while taking Trulicity. It is not known if Trulicity will harm their unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Trulicity passes into breast milk. Patients should not use Trulicity while breastfeeding without first talking to their healthcare provider.
- are taking other medicines including prescription and over-the-counter medicines, vitamins, and herbal supplements. Trulicity may affect the way some medicines work and some medicines may affect the way Trulicity works.
- are taking other medicines to treat diabetes, including insulin or sulfonylureas.

If patients take too much Trulicity, they should call their healthcare provider or go to the nearest emergency room right away.

The most common side effects with Trulicity may include: nausea, diarrhea, vomiting, abdominal pain and decreased appetite. Patients should talk to their healthcare provider about any side effect that bothers them or does not go away. These are not all the possible side effects of Trulicity. Patients should call their doctor for medical advice about side effects.

Patients are encouraged to report side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please click to access [Prescribing Information](#), including [Boxed Warning about possible thyroid tumors including thyroid cancer](#), and [Medication Guide](#).

Please see [Instructions for Use included with the pen](#).

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About Diabetes

Approximately 30 million Americans⁵ and an estimated 425 million adults worldwide have diabetes.⁶ Type 2 diabetes is the most common type internationally, accounting for an estimated 90 to 95 percent of all diabetes cases in the United States alone.⁵ Diabetes is a chronic disease that occurs when the body does not properly produce or use the hormone insulin.

About Lilly Diabetes

Lilly has been a global leader in diabetes care since 1923, when we introduced the world's first commercial insulin. Today we are building upon this heritage by working to meet the diverse needs of people with diabetes and those who care for them. Through research, collaboration and quality manufacturing we strive to make life better for people affected by diabetes. We offer a wide range of therapies and a continued determination to provide real solutions—from medicines and technologies to support programs and more. For the latest updates, visit <http://www.lillydiabetes.com/> or follow us on Twitter: [@LillyDiabetes](#) and Facebook: [LillyDiabetesUS](#).

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and www.lilly.com/newsroom/social-channels. P-LLY

Trulicity® is a registered trademark owned or licensed by Eli Lilly and Company, its subsidiaries, or affiliates.

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Trulicity as a treatment of type 2 diabetes, along with diet and exercise, in adults with type 2 diabetes and moderate to severe chronic kidney disease, and Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with study findings to date, that Trulicity will receive additional regulatory approvals or that Trulicity will prove to be commercially successful. 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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References:

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4. Tuttle KR, Bakris GL, Bulous RW, et al. Diabetic Kidney Disease: A Report From an ADA Consensus Conference. *Am J Kidney Dis*. 2014;64(4):510-533. Available at: [https://www.ajkd.org/article/S0272-6386\(14\)01065-8/pdf](https://www.ajkd.org/article/S0272-6386(14)01065-8/pdf).
5. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2017. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services; 2017.
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The Lilly logo is rendered in a vibrant red, cursive script. The letters are thick and fluid, with the 'L' being particularly large and stylized, leading into the 'i', 'l', 'l', 'y' which also flow together in a continuous, elegant hand.

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