



FDA approves Lilly's Foundayo™ (orforglipron), the only GLP-1 pill for weight loss that can be taken any time of day without food or water restrictions

April 1, 2026

Adults taking Foundayo lost an average of 27 pounds on the highest dose in the ATTAIN-1 clinical trial¹

Foundayo, Lilly's second FDA-approved obesity medicine, will be available via LillyDirect® with free home delivery, starting at \$25 per month with commercial coverage and \$149 for self-pay

INDIANAPOLIS, April 1, 2026 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced the U.S. Food and Drug Administration (FDA) approved Foundayo™ (orforglipron) for adults with obesity, or overweight with weight-related medical problems. When used alongside a reduced-calorie diet and increased physical activity, Foundayo helps individuals lose excess body weight and keep the weight off. Foundayo will be available via LillyDirect®, with prescriptions accepted immediately and shipping beginning April 6, followed shortly after by broad availability through U.S. retail pharmacies and telehealth providers.

"People living with obesity need treatment options that meet them where they are – and for many, a once-daily pill that can be taken with no food or water restrictions can offer them greater flexibility in how they approach their treatment," said Deborah Horn, DO, director of the Center for Obesity Medicine at McGovern Medical School at UTHealth Houston. "With Foundayo, we now have an oral option that delivered an average of 12.4% weight loss at the highest dose in clinical trials – addressing both the clinical realities of obesity and the practical challenges patients face every day."

Supported by the rigorous ATTAIN clinical trial program, Foundayo was proven to help people lose weight and keep it off. In the ATTAIN-1 trial, individuals taking the highest dose of Foundayo and who stayed on treatment lost an average of 27.3 pounds (12.4%) compared to 2.2 pounds (0.9%) with placebo.¹ Participants taking Foundayo, regardless of trial completion, lost an average of 25 pounds (11.1%), compared to 5.3 pounds (2.1%) with placebo.² In the ATTAIN program, Foundayo also led to reductions in many markers of cardiovascular risk, including waist circumference, non-HDL cholesterol, triglycerides and systolic blood pressure across all doses.

"Today, fewer than 1 in 10 people who could benefit from a GLP-1 are taking one, held back by access, stigma, perceived complexity or the belief that their condition isn't serious enough for treatment. We believe Foundayo can help level the playing field for those living with obesity or who are overweight and living with weight-related complications," said David A. Ricks, chair and CEO of Eli Lilly and Company. "As a convenient, once-daily oral pill that delivers meaningful weight loss, this is obesity care designed for the real world."

Lilly is committed to making Foundayo accessible and affordable. Eligible people with commercial insurance may pay as little as \$25 per month with the Foundayo savings card.³ Individuals opting for self-pay can access Foundayo starting at \$149 per month for the lowest dose. Additionally, eligible Medicare Part D individuals may be able to get Foundayo for \$50 per month, beginning as soon as July 1, 2026.

Use of Foundayo with other GLP-1 receptor agonist medicines is not recommended. It is not known whether Foundayo is safe and effective for use in children. 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 health care provider. 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. Please see **Indication and Safety Summary with Warning** below and full [Prescribing Information](#) and [Medication Guide](#).

"There is no single path that works for everyone living with overweight or obesity," said Joe Nadglowski, president and CEO of the Obesity Action Coalition. "New treatment options expand choice and help more people find care that fits their lives, their goals and where they are in their journey – whether they're just starting to explore treatment or looking for a different long-term approach."

Lilly has submitted orforglipron for weight management and/or type 2 diabetes in more than 40 countries and plans to launch in each country shortly after approval.

For more information about Foundayo, please visit www.foundayo.lilly.com.

About Foundayo (orforglipron)⁴

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.⁵ 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-1 and ATTAIN-2 clinical trial program

The ATTAIN Phase 3 global clinical development program for orforglipron has enrolled more than 4,500 people with obesity or overweight across two global registration trials.

ATTAIN-1 (NCT05869903) is a Phase 3, 72-week, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of orforglipron at various doses to placebo in adults with obesity, or overweight with at least one of the following comorbidities: hypertension, dyslipidemia, obstructive

sleep apnea or cardiovascular disease, who did not have diabetes. The trial randomized 3,127 participants across the U.S., Brazil, China, India, Japan, South Korea, Puerto Rico, Slovakia, Spain and Taiwan to receive various doses of orforglipron or placebo along with healthy diet and physical activity. The primary objective of the study was to demonstrate that orforglipron is superior to placebo in body weight reduction from baseline after 72 weeks.

ATTAIN-2 (NCT05872620) is a Phase 3, 72-week, randomized, double-blind, placebo-controlled trial comparing the efficacy and safety of various doses of orforglipron with placebo in adults with obesity or overweight and type 2 diabetes. The trial randomized over 1,600 participants across the U.S., Argentina, Australia, Brazil, China, Czechia, Germany, Greece, India, South Korea and Puerto Rico to receive various doses of orforglipron or placebo along with healthy diet and physical activity. The primary objective of the study was to demonstrate that orforglipron is superior to placebo in mean body weight change from baseline at 72 weeks.

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.

This summary provides basic information about Foundayo 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 doctor. Be sure to talk to your doctor or other healthcare provider about Foundayo and how to take it. Your doctor is the best person to help you decide if Foundayo is right for you.

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Endnotes and References

1. The efficacy estimand represents efficacy had all randomized participants remained on study intervention (with possible dose interruptions and modifications) for 72 weeks without initiating prohibited weight management treatments.⁴
2. The treatment-regimen estimand represents the estimated average treatment effect regardless of adherence to study intervention or initiation of prohibited weight management treatments.⁴
3. Terms and conditions apply. Learn more at foundayo.lilly.com.
4. Foundayo. Prescribing Information. Lilly USA, LLC.
5. 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 Agonist. *Diabetes Ther.* 2024 Apr;15(4):819-832. <https://doi.org/10.1007/s13300-024-01554-1>. Epub 2024 Feb 24. PMID: 38402332; PMCID: PMC10951152.

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](https://lilly.com) and [Lilly.com/news](https://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 Foundayo as a treatment for adults with obesity or some adults with overweight who also have 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 future study results will be consistent with study results to date, that Foundayo will receive additional regulatory approvals, or that Foundayo will be commercially successful. 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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