once weekly

# zepbound™

(tirzepatide) injection 0.5 mL

2.5 mg | 5 mg | 7.5 mg | 10 mg | 12.5 mg | 15 mg

# A teammate in obesity care


## Indication

Zepbound™ is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of:

- 30 kg/m$^2$ or greater (obesity) or
- 27 kg/m$^2$ or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes mellitus, obstructive sleep apnea, or cardiovascular disease).

## Limitations of Use:

- Zepbound contains tirzepatide. Coadministration with other tirzepatide-containing products or with any glucagon-like peptide-1 (GLP-1) receptor agonist is not recommended.
- The safety and efficacy of Zepbound in combination with other products intended for weight management, including prescription drugs, over-the-counter drugs, and herbal preparations, have not been established.
- Zepbound has not been studied in patients with a history of pancreatitis.

## Select Important Safety Information

**WARNING: RISK OF THYROID C-CELL TUMORS**

**In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.**

**Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound.**

Please see Important Safety Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Prescribing Information and Medication Guide.

# Meet Andrea*

## An adult struggling with obesity in your organization[1]

Not an actual patient.

Her BMI has reached **30 kg/m²**

She has **struggled multiple times**—and **attempted multiple methods**—to lose weight

She knows she needs to lose weight and **is interested in help**

BMI=body mass index.

Obesity is defined as BMI ≥30 kg/m².

*An adult with obesity you may see.

### Select Important Safety Information

**Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with tirzepatide.**

**Risk of Thyroid C-cell Tumors:** Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

**Reference: 1.** Zepbound. Prescribing Information. Lilly USA, LLC.

Please see Important Safety Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Prescribing Information and Medication Guide.

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# Powerful reductions in body weight[1]

## Adults lost an average of 20.9% of their body weight with Zepbound 15 mg vs 3.1% with placebo[1]

**Overall percentage change in body weight from baseline at 72 weeks[1,2]**

| -15.0% (-33.9 lb) | -19.5% (-44.4 lb) | -20.9% (-48.1 lb) | -3.1% (-6.6 lb) |
|---|---|---|---|
| **ZEPBOUND 5 mg** (n=630) From a mean baseline of 226.8 lb | **ZEPBOUND 10 mg** (n=636) From a mean baseline of 233.3 lb | **ZEPBOUND 15 mg** (n=630) From a mean baseline of 232.8 lb | **PLACEBO** (n=643) From a mean baseline of 231.0 lb |

P<0.001 for superiority of Zepbound vs placebo, controlled for type I error.[1]

**Treatment and placebo included a reduced-calorie diet and increased physical activity.[1]**

Studied in adults with obesity (BMI of ≥30 kg/m$^2$) or with overweight (BMI of ≥27 kg/m$^2$) with at least 1 weight-related comorbidity, excluding type 2 diabetes.[1]

The percentage change in body weight by dose (Zepbound 10 mg and 15 mg) was a coprimary endpoint.[3]

ITT population includes all randomly assigned patients. The missing values were imputed by a hybrid approach using retrieved dropouts from the same treatment group (if missing not due to COVID-19) or using all non-missing data from the same treatment group assuming missing at random (for missing solely due to COVID-19). Least-squares mean from ANCOVA adjusted for baseline value and other stratification factors.[1]

In a separate weight-reduction study of adults with a BMI of ≥27 kg/m$^2$ and type 2 diabetes, the overall percentage change in body weight from baseline at 72 weeks was -12.8% (10 mg), -14.7% (15 mg), and -3.2% (placebo). Mean baseline weights were 222.4 lb (10 mg), 219.6 lb (15 mg), and 224.2 lb (placebo).[1,4]

**SURMOUNT-1 study design:**
SURMOUNT-1 was a 72-week, double-blind, placebo-controlled, phase 3 trial that randomized 2539 adult patients with a BMI of ≥30 kg/m$^2$ or ≥27 kg/m$^2$ and at least 1 weight-related comorbid condition (study excluded patients with type 1 diabetes or type 2 diabetes), to receive once-weekly subcutaneous Zepbound 5 mg, 10 mg, 15 mg, or placebo (1:1:1:1 ratio), including a 20-week dose-escalation period. Treatment was an adjunct to a reduced-calorie diet and increased physical activity.* Mean baseline body weight for Zepbound 5 mg was 226.8 lb, for Zepbound 10 mg 233.3 lb, for Zepbound 15 mg 232.8 lb, and for placebo 231.0 lb.[1-3] Coprimary endpoints were to demonstrate that Zepbound 10 mg and/or 15 mg are superior to placebo for mean percent change in body weight from baseline and percentage of study participants who achieved ≥5% body weight reduction at 72 weeks.[1,3]

**SURMOUNT-2 study design:**
SURMOUNT-2 was a 72-week, double-blind, placebo-controlled, phase 3 trial that randomized 938 adult patients with a BMI of ≥27 kg/m$^2$ and type 2 diabetes to receive once-weekly subcutaneous Zepbound 10 mg, 15 mg, or placebo (1:1:1 ratio), including a 20-week dose-escalation period. Treatment with Zepbound or placebo was an adjunct to a reduced-calorie diet and increased physical activity.* Patients included in the trial were treated with diet and exercise alone or with any oral anti-hyperglycemic agent except DPP-4 inhibitors or GLP-1 receptor agonists. Patients taking injectable therapies for type 2 diabetes were excluded from the study. Mean baseline body weight was 222.4 lb for Zepbound 10 mg, 219.6 lb for Zepbound 15 mg, and 224.2 lb for placebo.[1,4,5] Coprimary endpoints were to demonstrate that Zepbound 10 mg and/or 15 mg are superior to placebo for mean percent change in body weight from baseline and percentage of study participants who achieved ≥5% body weight reduction at 72 weeks.[1,5]

ANCOVA=analysis of covariance; DPP-4=dipeptidyl peptidase-4; ITT=intent-to-treat.

*Reduced-calorie diet (approximately 500 kcal/day deficit) and increased physical activity counseling (recommended to a minimum of 150 min/week).[1]

## Select Important Safety Information

**Severe Gastrointestinal Disease:** Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1.0%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

**References: 1.** Zepbound. Prescribing Information. Lilly USA, LLC. **2.** Data on File. Lilly USA, LLC. DOF-ZP-US-0001. **3.** Jastreboff AM, et al. *N Engl J Med*. 2022;387(3):205-216. **4.** Data on File. Lilly USA, LLC. DOF-ZP-US-0005. **5.** Garvey WT, et al. *Lancet*. 2023;402(10402):613-626.

Please see Important Safety Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Prescribing Information and Medication Guide.

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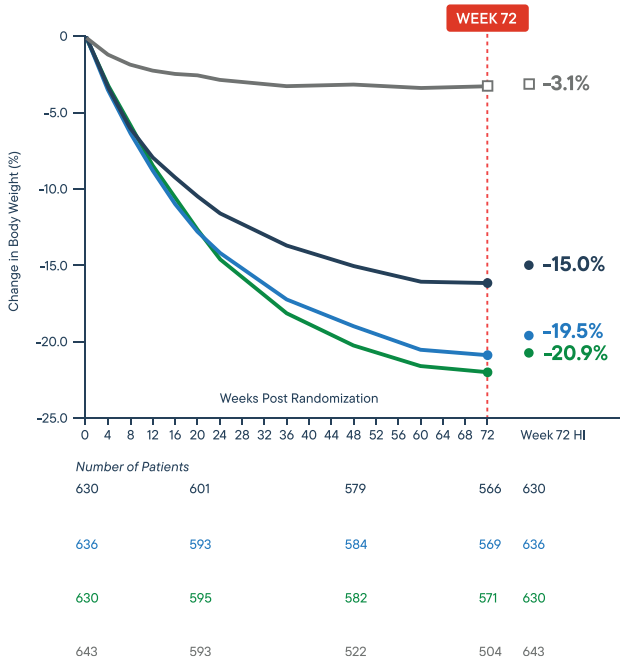
# Powerful reductions in body weight (%) sustained through 72 weeks[1]

## Adults lost an average of 20.9% of their body weight with Zepbound 15 mg vs 3.1% with placebo[1]

In a pooled analysis, adults taking Zepbound 10 mg and 15 mg achieved an average weight reduction of 28.2 lb vs 6.0 lb with placebo at week 20.[2,3]

### Percentage change in body weight over time from baseline to week 72[1,4,5]




**Zepbound 5 mg**
**Mean baseline weight=226.8 lb**

**Zepbound 10 mg**
**Mean baseline weight=233.3 lb**

**Zepbound 15 mg**
**Mean baseline weight=232.8 lb**

**Placebo**
**Mean baseline weight=231.0 lb**

P<0.001 for superiority of Zepbound vs placebo, controlled for type I error.[1]

**Treatment and placebo included a reduced-calorie diet and increased physical activity.[1]**

Studied in adults with obesity (BMI of ≥30 kg/m$^2$) or with overweight (BMI of ≥27 kg/m$^2$) with at least 1 weight-related comorbidity, excluding type 2 diabetes.[1]

The percentage change in body weight by dose (Zepbound 10 mg and 15 mg) was a coprimary endpoint.[3]

ITT population includes all randomly assigned patients. Data represent observed mean percent changes in body weight from week 0 to 72 and least-squares mean percent change at week 72. ANCOVA was performed for percent weight change from baseline at week 72 with hybrid imputation.[1]

In a separate weight-reduction study of adults with a BMI of ≥27 kg/m$^2$ and type 2 diabetes, the overall percentage change in body weight from baseline at 72 weeks was -12.8% (10 mg), -14.7% (15 mg), and -3.2% (placebo). Mean baseline weights were 222.4 lb (10 mg), 219.6 lb (15 mg), and 224.2 lb (placebo).[1,6]

## Select Important Safety Information

**Acute Kidney Injury:** Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound, including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

**References: 1.** Zepbound. Prescribing Information. Lilly USA, LLC. **2.** Data on File. Lilly USA, LLC. DOF-ZP-US-0012. **3.** Jastreboff AM, et al. *N Engl J Med.* 2022;387(3):205-216. **4.** Data on File. Lilly USA, LLC. DOF-ZP-US-0001. **5.** Data on File. Lilly USA, LLC. DOF-ZP-US-0006. **6.** Data on File. Lilly USA, LLC. DOF-ZP-US-0005.

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# Adverse reactions pooled from the SURMOUNT-1 and SURMOUNT-2 trials[1]

## Adverse reactions (≥2% and greater than placebo) in Zepbound-treated adults[1]

| ADVERSE REACTION | ZEPBOUND 5 mg (n=630) | ZEPBOUND 10 mg (n=948) | ZEPBOUND 15 mg (n=941) | PLACEBO (n=958) |
|---|---|---|---|---|
| Nausea | 25% | 29% | 28% | 8% |
| Diarrhea | 19% | 21% | 23% | 8% |
| Vomiting | 8% | 11% | 13% | 2% |
| Constipation | 17% | 14% | 11% | 5% |
| Abdominal pain | 9% | 9% | 10% | 5% |
| Dyspepsia | 9% | 9% | 10% | 4% |
| Injection-site reactions | 6% | 8% | 8% | 2% |
| Fatigue | 5% | 6% | 7% | 3% |
| Hypersensitivity reactions | 5% | 5% | 5% | 3% |
| Eructation | 4% | 5% | 5% | 1% |
| Hair loss | 5% | 4% | 5% | 1% |
| Gastroesophageal reflux disease | 4% | 4% | 5% | 2% |
| Flatulence | 3% | 3% | 4% | 2% |
| Abdominal distention | 3% | 3% | 4% | 2% |
| Dizziness | 4% | 5% | 4% | 2% |
| Hypotension | 1% | 1% | 2% | 0% |

The most common adverse reactions occurring more frequently with Zepbound than with placebo were GI related[1]

The majority of reports of nausea, vomiting, and/or diarrhea occurred during dose escalation and decreased over time[1]

Studied in adults with obesity (BMI of ≥30 kg/m$^2$) or with overweight (BMI of ≥27 kg/m$^2$) with at least 1 weight-related comorbidity.[1]

In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m$^2$, hypoglycemia (plasma glucose <54 mg/dL) was reported in 4.2% of Zepbound-treated patients vs 1.3% of placebo-treated patients.

In a trial of Zepbound in adults with obesity/overweight without type 2 diabetes mellitus, there was no systematic capturing of hypoglycemia, but plasma glucose <54 mg/dL was reported in 0.3% of Zepbound-treated patients versus no placebo-treated patients.[1]

This table shows common adverse reactions associated with the use of Zepbound in two phase 3 placebo-controlled trials. Percentages reflect the number of adult patients who reported at least 1 treatment-emergent occurrence of the adverse reaction.[1-3]

## Treatment discontinuation rates[1]

| TREATMENT DISCONTINUATION | ZEPBOUND 5 mg (n=630) | ZEPBOUND 10 mg (n=948) | ZEPBOUND 15 mg (n=941) | PLACEBO (n=958) |
|---|---|---|---|---|
| **Due to ARs** | 4.8% | 6.3% | 6.7% | 3.4% |
| **Due to GI ARs** | 1.9% | 3.3% | 4.3% | 0.5% |

The majority of adult patients who discontinued Zepbound due to adverse reactions did so during the first few months of treatment due to gastrointestinal adverse reactions.[1]

AR=adverse reaction; GI=gastrointestinal.

**References: 1.** Zepbound. Prescribing Information. Lilly USA, LLC. **2.** Jastreboff AM, et al. *N Engl J Med.* 2022;387(3):205-216. **3.** Garvey WT, et al. *Lancet*. 2023;402(10402):613-626.

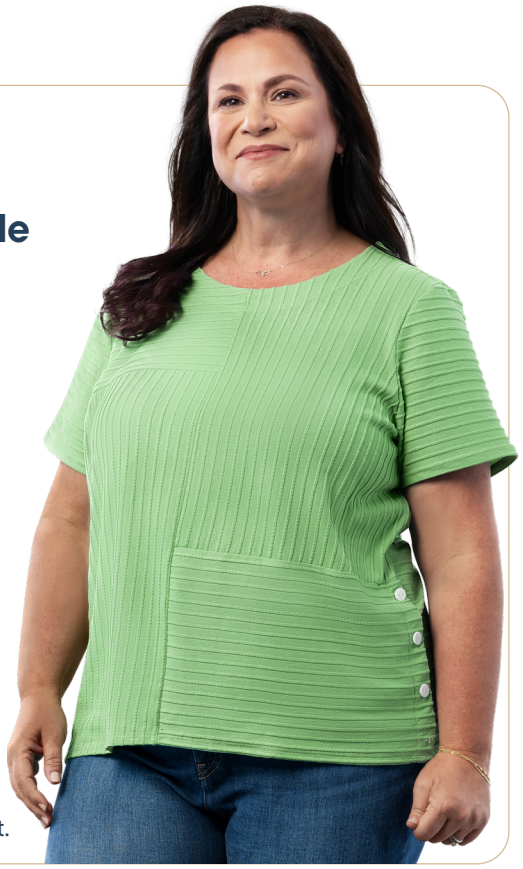
# Are your employees getting the care they need?

**Because obesity is a complex disease, some employees may need a more comprehensive approach to treatment that includes both lifestyle interventions* and anti-obesity medications[1,2]**

## Weight bias and stigma[3]

Clear evidence supports that people with obesity can experience weight stigma and bias in various aspects of daily life

Negative perceptions of people with obesity exist in the workplace; employers and coworkers may perceive employees with obesity as less competent, lazy, and lacking in self-discipline



Not an actual patient.

**48% of employers have opted in to coverage for branded anti-obesity medications[4†]**

*A structured lifestyle intervention program for weight loss (or lifestyle therapy) includes a reduced-calorie healthy meal plan, physical activity, and behavioral interventions.

†Based on a 2023 survey of 109 employers with 5000 to 100,000+ US employees and 5.4 million covered lives.[4] Respondents were asked if their organization provided insurance coverage for branded weight loss medications.[4]

### Select Important Safety Information

**Acute Gallbladder Disease:** Treatment with Zepbound and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1.0% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

**References: 1.** Garvey WT, et al. *Endocr Pract.* 2016;22(suppl 3):1-203. **2.** Apovian CM, et al. *J Clin Endocrinol Metab.* 2015;100(2):342-362. **3.** *Understanding Obesity Stigma.* Obesity Action Coalition; 2020. Accessed August 15, 2023. https://www.obesityaction.org/wp-content/uploads/Understanding-Obesity-Stigma-Brochure20200313.pdf **4.** Data on File. Lilly USA, LLC. DOF-ZP-US-0011.

Please see Important Safety Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Prescribing Information and Medication Guide.

## Important Safety Information

**WARNING: RISK OF THYROID C-CELL TUMORS**

**In rats, tirzepatide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures. It is unknown whether Zepbound causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans as human relevance of tirzepatide-induced rodent thyroid C-cell tumors has not been determined.**

**Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound.**

**Zepbound is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2, and in patients with known serious hypersensitivity to tirzepatide or any of the excipients in Zepbound. Serious hypersensitivity reactions including anaphylaxis and angioedema have been reported with tirzepatide.**

**Risk of Thyroid C-cell Tumors:** Counsel patients regarding the potential risk for MTC with the use of Zepbound and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Zepbound. Such monitoring may increase the risk of unnecessary procedures, due to the low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin values may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

**Severe Gastrointestinal Disease:** Use of Zepbound has been associated with gastrointestinal adverse reactions, sometimes severe. In clinical trials, severe gastrointestinal adverse reactions were reported more frequently among patients receiving Zepbound (5 mg 1.7%, 10 mg 2.5%, 15 mg 3.1%) than placebo (1.0%). Zepbound has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis, and is therefore not recommended in these patients.

**Acute Kidney Injury:** Use of Zepbound has been associated with acute kidney injury, which can result from dehydration due to gastrointestinal adverse reactions to Zepbound, including nausea, vomiting, and diarrhea. In patients treated with GLP-1 receptor agonists, there have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis. Some of these events have been reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function in patients reporting adverse reactions to Zepbound that could lead to volume depletion.

**Acute Gallbladder Disease:** Treatment with Zepbound and GLP-1 receptor agonists is associated with an increased occurrence of acute gallbladder disease. In clinical trials of Zepbound, cholelithiasis was reported in 1.1% of Zepbound-treated patients and 1.0% of placebo-treated patients, cholecystitis was reported in 0.7% of Zepbound-treated patients and 0.2% of placebo-treated patients, and cholecystectomy was reported in 0.2% of Zepbound-treated patients and no placebo-treated patients. Acute gallbladder events were associated with weight reduction. If cholecystitis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated.

**Acute Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists, or tirzepatide. In clinical trials of tirzepatide for a different indication, 14 events of acute pancreatitis were confirmed by adjudication in 13 tirzepatide-treated patients (0.23 patients per 100 years of exposure) versus 3 events in 3 comparator-treated patients (0.11 patients per 100 years of exposure). In Zepbound clinical trials, 0.2% of Zepbound-treated patients had acute pancreatitis confirmed by adjudication (0.14 patients per 100 years of exposure) versus 0.2% of placebo-treated patients (0.15 patients per 100 years of exposure). Zepbound has not been studied in patients with a prior history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on Zepbound. Observe patients for signs and symptoms, including persistent severe abdominal pain sometimes radiating to the back, which may or may not be accompanied by vomiting. If pancreatitis is suspected, discontinue Zepbound and initiate appropriate management. If the diagnosis of pancreatitis is confirmed, Zepbound should not be restarted.

**Hypersensitivity Reactions:** There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylaxis, angioedema) in patients treated with tirzepatide. In Zepbound clinical trials, 0.1% of Zepbound-treated patients had severe hypersensitivity reactions compared to no placebo-treated patients. If hypersensitivity reactions occur, advise patients to promptly seek medical attention and discontinue use of Zepbound. Do not use in patients with a previous serious hypersensitivity reaction to tirzepatide or any of the excipients in Zepbound. Use caution in patients with a history of angioedema or anaphylaxis with a GLP-1 receptor agonist because it is unknown if such patients will be predisposed to these reactions with Zepbound.

**Hypoglycemia:** Zepbound lowers blood glucose and can cause hypoglycemia. In a trial of patients with type 2 diabetes mellitus and BMI ≥27 kg/m$^2$, hypoglycemia (plasma glucose <54mg/dL) was reported in 4.2% of Zepbound-treated patients versus 1.3% of placebo-treated patients. In this trial, patients taking Zepbound in combination with an insulin secretagogue (e.g., sulfonylurea) had increased risk of hypoglycemia (10.3%) compared to Zepbound-treated patients not taking a sulfonylurea (2.1%). Hypoglycemia has also been associated with Zepbound and GLP-1 receptor agonists in adults without type 2 diabetes mellitus. There is also increased risk of hypoglycemia in patients treated with tirzepatide in combination with insulin. Inform patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia. In patients with diabetes mellitus, monitor blood glucose prior to starting Zepbound and during Zepbound treatment. The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogue) or insulin.

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Please see Instructions for Use included with the pen.

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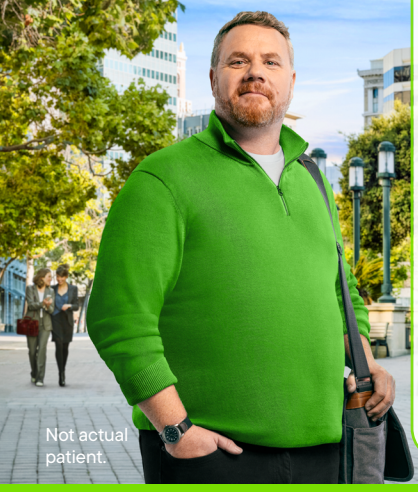


# Obesity care is healthcare

## Consider how Zepbound can work for your organization

- Because obesity is a complex disease, some employees may need a more comprehensive approach to treatment that includes both lifestyle interventions* and anti-obesity medications[1,2]
- Zepbound offers powerful reductions in body weight vs placebo at 72 weeks[3]
- 48% of employers have opted in to coverage for branded anti-obesity medications[4†]

**See how obesity impacts employees and connect with a Lilly employer consultant**

**For adults with obesity (BMI ≥30 kg/m²) or with overweight (BMI ≥27 kg/m²) with at least 1 weight-related comorbidity, in addition to a reduced-calorie diet and increased physical activity.[3]**

*A structured lifestyle intervention program for weight loss (or lifestyle therapy) includes a reduced-calorie healthy meal plan, physical activity, and behavioral interventions.[1]

†Based on a 2023 survey of 109 employers with 5000 to 100,000+ US employees and 5.4 million covered lives.[4] Respondents were asked if their organization provided insurance coverage for branded weight loss medications.[4]

## Important Safety Information (continued)

**Diabetic Retinopathy Complications in Patients with Type 2 Diabetes Mellitus:** Rapid improvement in glucose control has been associated with a temporary worsening of diabetic retinopathy. Tirzepatide has not been studied in patients with non-proliferative diabetic retinopathy requiring acute therapy, proliferative diabetic retinopathy, or diabetic macular edema. Patients with a history of diabetic retinopathy should be monitored for progression of diabetic retinopathy.

**Suicidal Behavior and Ideation:** Suicidal behavior and ideation have been reported in clinical trials with other chronic weight management products. Monitor patients treated with Zepbound for the emergence or worsening of depression, suicidal thoughts or behaviors, and/or any unusual changes in mood or behavior. Discontinue Zepbound in patients who experience suicidal thoughts or behaviors. Avoid Zepbound in patients with a history of suicidal attempts or active suicidal ideation.

**The most common adverse reactions,** reported in ≥5% of patients treated with Zepbound are: nausea, diarrhea, vomiting, constipation, abdominal pain, dyspepsia, injection site reactions, fatigue, hypersensitivity reactions, eructation, hair loss, and gastroesophageal reflux disease.

**Drug Interactions:** Zepbound lowers blood glucose. When initiating Zepbound, consider reducing the dose of concomitantly administered insulin secretagogues (e.g., sulfonylureas) or insulin to reduce the risk of hypoglycemia. Zepbound delays gastric emptying and thereby has the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with Zepbound. Monitor patients on oral medications dependent on threshold concentrations for efficacy and those with a narrow therapeutic index (e.g., warfarin) when concomitantly administered with Zepbound.

**Pregnancy:** Advise pregnant patients that weight loss is not recommended during pregnancy and to discontinue Zepbound when a pregnancy is recognized. Available data with tirzepatide in pregnant patients are insufficient to evaluate for a drug-related risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. Based on animal reproduction studies, there may be risks to the fetus from exposure to tirzepatide during pregnancy. There will be a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Zepbound (tirzepatide) during pregnancy. Pregnant patients exposed to Zepbound and healthcare providers are encouraged to contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).

**Lactation:** There are no data on the presence of tirzepatide or its metabolites in animal or human milk, the effects on the breastfed infant, or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Zepbound and any potential adverse effects on the breastfed infant from Zepbound or from the underlying maternal condition.

**Females and Males of Reproductive Potential:** Use of Zepbound may reduce the efficacy of oral hormonal contraceptives due to delayed gastric emptying. This delay is largest after the first dose and diminishes over time. Advise patients using oral hormonal contraceptives to switch to a non-oral contraceptive method or add a barrier method of contraception, for 4 weeks after initiation with Zepbound and for 4 weeks after each dose escalation.

**Pediatric Use:** The safety and effectiveness of Zepbound have not been established in pediatric patients less than 18 years of age.

Please see accompanying Prescribing Information, including Boxed Warning about possible thyroid tumors, including thyroid cancer, and Medication Guide.

Please see Instructions for Use included with the pen.

ZP HCP ISI 08NOV2023

**References: 1.** Garvey WT, et al. *Endocr Pract.* 2016;22(suppl 3):1-203. **2.** Apovian CM, et al. *J Clin Endocrinol Metab.* 2015;100(2):342-362. **3.** Zepbound. Prescribing Information. Lilly USA, LLC. **4.** Data on File. Lilly USA, LLC. DOF-ZP-US-0011.



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