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# What is Zepbound?<sup>1</sup>

Zepbound (tirzepatide) is an injectable prescription medicine that may help adults with obesity, or with excess weight (overweight) who also have weight-related medical problems, lose weight and keep it off. Zepbound 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 when taken with other prescription, over-the-counter, or herbal weight loss products. It is not known if Zepbound can be used in people who have had pancreatitis. It is not known if Zepbound is safe and effective for use in children under 18 years of age.

To screen for obesity, doctors use different approaches. A common approach is the body mass index (BMI)—a measure of obesity and an estimate of body fat based on height and weight.<sup>1,3,4,5</sup>

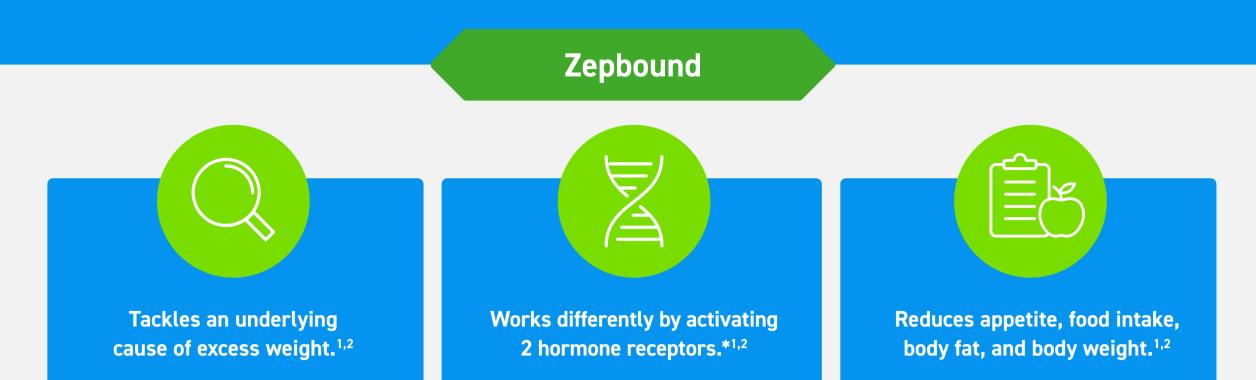
Underweight  $< 18.5 \text{ kg/m}^2$ 

**Healthy Weight** 18.5-24.9 kg/m<sup>2</sup>

**Overweight** 25.0-29.9 kg/m<sup>2</sup>

**Obesity** > 30.0 kg/m<sup>2</sup>

Zepbound is indicated for use in adults with obesity (BMI >30 kg/m<sup>2</sup>) or overweight (BMI  $\geq 27 \text{ kg/m}^2$ ) with a weight-related medical condition.<sup>1</sup>



\*Hormone receptors: glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1).

WARNING: Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats, Zepbound and medicines that work like Zepbound caused thyroid tumors, including thyroid cancer. It is not known if Zepbound will cause thyroid tumors, or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people. Do not take Zepbound if you or any of your family have ever had MTC or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

SELECT SAFETY INFORMATION: Do not use Zepbound if you or any of your family have ever had a type of thyroid cancer called MTC or if you have an endocrine system condition called MEN 2, or if you have had a serious allergic reaction to tirzepatide or any of the ingredients in Zepbound.

## Weight Loss with Zepbound

People lost up to an average of 48 lbs at the highest dose of Zepbound\*<sup>+1,6,7</sup>

In a 17-month study of 2,539 adults with obesity or with excess weight and weight-related medical problems, people taking Zepbound experienced substantial weight loss:<sup>1</sup>

34-lb weight loss with diet, exercise, and Zepbound 5 mg\*†

44-lb weight loss with diet, exercise, and Zepbound 10 mg\*<sup>†</sup>

48-lb weight loss with diet, exercise, and Zepbound 15 mg\*t

7-lb weight loss with diet, exercise, and placebo\*

\*Treatment and placebo included reduced-calorie diet and increased physical activity.

<sup>+</sup>Individual results may vary. In a 72-week study of adults without diabetes, average weight loss was 15.0% (34 lbs) for 5 mg, 19.5% (44 lbs) for 10 mg, 20.9% (48 lbs) for 15 mg, and 3.1% (7 lbs) for placebo. In a 72-week study of adults with diabetes, average weight loss was 12.8% (28 lbs) for 10 mg, 14.7% (33 lbs) for 15 mg, and 3.2% (7 lbs) for placebo.

Average starting weight was 231 lbs in adults without diabetes and 222 lbs in adults with diabetes.

#### **SELECT SAFETY INFORMATION**

Zepbound can 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.

To learn more about Zepbound, including how to access it, visit <u>www.zepbound.lilly.com</u>.

#### **INDICATION AND SAFETY SUMMARY WITH WARNINGS**

Zepbound™ (ZEHP-bownd) is an injectable prescription medicine that may help adults with obesity, or with excess weight (overweight) who also have weight-related medical problems, lose weight and keep it off. 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 when taken with other prescription, over-the-counter, or herbal weight loss products. It is not known if Zepbound can be used in people who have had pancreatitis. It is not known if Zepbound is safe and effective for use in children under 18 years of age.

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.

#### **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 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 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 insulin or sulfonylureas 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?
- 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.
- 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. ٠
- 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.

#### 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.

#### ZP CON CBS 08N0V2023

### References

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- 2. Lean ME, Malkova D. Altered gut and adipose tissue hormones in overweight and obese individuals: cause or consequence? *Int J Obes (Lond)*. 2016;40(4):622-632
- 3. Schmidt M, Johannesdottir SA, Lemeshow S, et al. Obesity in young men, and individual and combined risks of type 2 diabetes, cardiovascular morbidity and death before 55 years of age: a Danish 33-year follow-up study. BMJ Open. 2013;3:e002698. doi: 10.1136/bmjopen-2013-002698
- 4. Assessing your weight and health risk. National Heart, Lung, and Blood Institute. Accessed May 30, 2023. https://www.nhlbi.nih.gov/health/educational/lose\_wt/risk.htm
- 5. Jensen MD, Ryan DH, Apovian CM, et al. 2013 AHA/ACC/TOS guideline for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation. 2014;129(25 suppl 2):S102-S138.
- 6. Data on File. Lilly USA, LLC. DOF-ZP-US-0001
- 7. Data on File. Lilly USA, LLC. DOF-ZP-US-0005

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