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– **BOXED WARNING** (WHAT IS THIS?)

**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 [see *Warnings and Precautions (5.1)* and *Nonclinical Toxicology (13.1)*].
- 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) [see *Contraindications (4)*]. 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 [see *Contraindications (4)* and *Warnings and Precautions (5.1)*].

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**Medication Guide**  
**ZEPBOUND™ (ZEHP-bownd)**  
**(tirzepatide)**  
**injection, for subcutaneous use**

**What is the most important information I should know about ZEPBOUND?**

**ZEPBOUND may cause serious side effects, including:**

- **Possible thyroid tumors, including cancer.** 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 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 Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

**What is ZEPBOUND?**

- ZEPBOUND 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.

**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.
- you have had a serious allergic reaction to tirzepatide or any of the ingredients in ZEPBOUND. See the end of this Medication Guide for a complete list of ingredients in ZEPBOUND.

**Before using ZEPBOUND, tell your healthcare provider about all of your medical conditions, including if you:**

- have or have had problems with your pancreas or kidneys.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have a history of diabetic retinopathy.
- are pregnant or plan to become pregnant. ZEPBOUND may harm your unborn baby. Tell your healthcare provider if you become pregnant 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 Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979).
  - **Birth control pills by mouth may not work as well while using ZEPBOUND.** If you take birth control pills by mouth, 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. Talk to your healthcare provider about birth control methods that may be right for you while using ZEPBOUND.
- are breastfeeding or plan to breastfeed. It is not known if ZEPBOUND passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using ZEPBOUND.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. ZEPBOUND may affect the way some medicines work, and some medicines may affect the way ZEPBOUND works.

**Before using ZEPBOUND, 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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

### How should I use ZEPBOUND?

- Read the **Instructions for Use** that comes with ZEPBOUND.
- Use ZEPBOUND exactly as your healthcare provider tells you to. A healthcare provider should show you how to prepare to inject your dose of ZEPBOUND before injecting the first time.
- 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.**
- You may change the day of the week you use ZEPBOUND as long as the time between the 2 doses is at least **3 days (72 hours)**.
- If you miss a dose of ZEPBOUND, take the missed dose as soon as possible within 4 days (96 hours) after the missed dose. If more than 4 days have passed, skip the missed dose and take your next dose on the regularly scheduled day. **Do not** take **2** doses of ZEPBOUND within **3** days (72 hours) of each other.
- ZEPBOUND may be taken with or without food.
- Change (rotate) your injection site with each weekly injection. You may use the same area of your body but be sure to choose a different injection site in that area. **Do not** use the same site for each injection.
- In case of overdose, get medical help or contact a Poison Center expert right away at 1-800-222-1222. Advice is also available online at [poisonhelp.org](http://poisonhelp.org).

### What are the possible side effects of ZEPBOUND?

ZEPBOUND may cause serious side effects, including:

- See “**What is the most important information I should know about ZEPBOUND?**”
- **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)
  - clay-colored stools
- **inflammation of your 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
  - 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
  - blurred vision
  - slurred speech
  - shakiness
  - anxiety, irritability, or mood changes
  - hunger
  - weakness

- headache
- fast heartbeat
- 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 any changes in your mood, behaviors, feelings, or thoughts. Call your healthcare provider right away if you have any changes to your mental health that are new, worse, or worry you.

**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
- heartburn

Talk to your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of ZEPBOUND. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store ZEPBOUND?**

- Store ZEPBOUND in the refrigerator between 36°F to 46°F (2°C to 8°C). Store ZEPBOUND in the original carton until use to protect it from light.
- If needed, each single-dose pen can be stored at room temperature up to 86°F (30°C) for up to 21 days. If ZEPBOUND is stored at room temperature, it should not be returned to the refrigerator.
- Discard if not used within 21 days after removing from the refrigerator.
- Do not freeze ZEPBOUND. Do not use ZEPBOUND if frozen.

**Keep ZEPBOUND and all medicines out of the reach of children.**

**General information about the safe and effective use of ZEPBOUND.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ZEPBOUND for a condition for which it was not prescribed. Do not give ZEPBOUND to other people, even if they have the same condition you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ZEPBOUND that is written for health professionals.

**What are the ingredients in ZEPBOUND?**

**Active ingredient:** tirzepatide

**Inactive ingredients:** sodium chloride, sodium phosphate dibasic heptahydrate, and water for injection. Hydrochloric acid solution and/or sodium hydroxide solution may have been added to adjust the pH. ZEPBOUND™ is a trademark of Eli Lilly and Company.

**Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA**

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For more information, go to [www.zepbound.com](http://www.zepbound.com) or call 1-800-545-5979.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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**+ INSTRUCTIONS FOR USE**

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