

GENERIC NAME:

Tirzepatide Vials (Zepbound)

Pronunciación

(tir ZEP a tide)

Brand Name:**Warning**

- This drug has been shown to cause thyroid cancer in some animals. It is not known if this happens in humans. If thyroid cancer happens, it may be deadly if not found and treated early. Call your doctor right away if you have a neck mass, trouble breathing, trouble swallowing, or have hoarseness that will not go away.
- Do not use this drug if you have a health problem called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2), or if you or a family member have had thyroid cancer.
- Have your blood work checked and thyroid ultrasounds as you have been told by your doctor.

What is this drug used for?

- It is used to help with weight loss in certain people.
- It is used to treat sleep apnea in certain patients.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you have ever had pancreatitis.
- If your stomach empties slowly or you have trouble digesting food.
- If you are using another drug that has the same drug in it.
- If you are using another drug like this one. If you are not sure, ask your doctor or pharmacist.
- If you have or have ever had depression or thoughts of suicide.

This is not a list of all drugs or health problems that interact with this drug.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Follow the diet and exercise plan that your doctor told you about.
- Talk with your doctor before you drink alcohol.
- Birth control pills may not work as well to prevent pregnancy. If you take birth control pills, you may need to switch to another type of hormone-based birth control like a vaginal ring if your doctor tells you to. If another type of hormone-based birth control is not an option, use some other kind of birth control also, like a condom. Do this for 4 weeks after starting this drug and for 4 weeks each time the dose is raised.
- This drug may prevent other drugs taken by mouth from getting into the body. If you take other drugs by mouth, you may need to take them at some other time than this drug. Talk with your doctor.
- Do not share with another person even if the needle has been changed. Sharing your tray or pen may pass infections from one person to another. This includes infections you may not know you have.
- If you cannot drink liquids by mouth or if you have upset stomach, throwing up, or diarrhea that does not go away, you need to avoid getting dehydrated. Contact your doctor to find out what to do. Dehydration may lead to low blood pressure or to new or worsening kidney problems.
- If you will be having any surgery or procedure, talk with your doctor. This drug may raise the risk of food getting

into the lungs during surgery or other procedures that use anesthesia or deep sedation. You may need to stop this drug before these types of surgery or procedures.

- If you have high blood sugar (diabetes), you will need to watch your blood sugar closely.
- This drug may cause harm to the unborn baby if you take it while you are pregnant. Weight loss during pregnancy may also cause harm to an unborn baby. If you are pregnant or you get pregnant while taking this drug, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- It is given as a shot into the fatty part of the skin on the top of the thigh, belly area, or upper arm.
- Do not give into a muscle or vein.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- It is important to have the right syringe to measure your dose. If you do not have the right syringe or you are not sure, talk with your pharmacist.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.
- Take the same day each week.
- Move site where you give the shot each time.
- Take with or without food.
- Wash your hands before and after use.
- Do not use if the solution is leaking or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Each vial is for 1 use only. Throw away any part of the used vial after the dose is given.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

What are some other side effects of this drug?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of gallbladder problems like pain in the upper right belly area, right shoulder area, or between the shoulder blades; yellow skin or eyes; fever with chills; bloating; or very upset stomach or throwing up.
- Dizziness or passing out.
- A fast heartbeat.
- Change in eyesight.
- New or worse behavior or mood changes like depression or thoughts of suicide.
- Feeling anxious or irritable.
- Slurred speech.
- Mood changes.
- Low blood sugar can happen. The chance may be raised when this drug is used with other drugs for diabetes. Signs may be dizziness, headache, feeling sleepy or weak, shaking, fast heartbeat, confusion, hunger, or sweating. Call your doctor right away if you have any of these signs. Follow what you have been told to do for low blood sugar. This may include taking glucose tablets, liquid glucose, or some fruit juices.
- Severe and sometimes deadly pancreas problems (pancreatitis) have happened with this drug. Call your doctor right away if you have severe stomach pain, severe back pain, or severe upset stomach or throwing up.
- Kidney problems have happened. Sometimes, these may need to be treated in the hospital or with dialysis. Tell your doctor right away if you have signs of kidney problems like being unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.

How do I store and/or throw out this drug?

Monograph continued.....

- Store in a refrigerator. Do not freeze.
- Do not use if it has been frozen.
- If needed, each vial may be stored at room temperature for up to 21 days. If you store at room temperature, throw away any part not used after 21 days.
- Do not put this drug back in the refrigerator after it has been stored at room temperature.
- Protect from heat.
- Store in the original container to protect from light.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at <https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms>.

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 some adults with overweight who also have weight-related medical problems, to lose excess body weight and keep the weight off.
 - moderate to severe obstructive sleep apnea (OSA) and obesity to improve their OSA.
- 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 for use in children.

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 scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation).
- 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 an insulin or sulfonylurea 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.
- Use ZEPBOUND with a reduced-calorie diet and increased physical activity.
- 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.

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 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, or mood changes
 - hunger
 - weakness
 - 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.
- **food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation).** ZEPBOUND may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking ZEPBOUND before you are scheduled to have surgery or other procedures.

The most common side effects of ZEPBOUND include:

- | | | |
|----------------|----------------------------|----------------------|
| • nausea | • stomach (abdominal) pain | • allergic reactions |
| • diarrhea | • indigestion | • belching |
| • vomiting | • injection site reactions | • hair loss |
| • constipation | • feeling tired | • 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 doctor 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 or single-dose vial 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 registered trademark of Eli Lilly and Company.

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

Copyright © 2023, YYYY, Eli Lilly and Company. All rights reserved.

For more information, go to www.zepbound.com or call 1-800-545-5979.

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

Revised: 12/2024

B2.0-NL-ZEP-0003-MG-YYYYMMDD

Notice to Consumers in the state of Texas

Do not flush unused medications or pour down a sink or drain.

Written information about this prescription has been provided for you. Please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions.

No deseche los medicamentos no utilizados ni los vierta en un fregadero o desagüe.

Se le ha proporcionado información escrita sobre esta receta. Lea esta información antes de tomar el medicamento. Si tiene preguntas sobre esta receta, un farmacéutico está disponible durante el horario comercial normal para responderlas. El número de teléfono de la farmacia está en la etiqueta.