

**IMPORTANT: HOW TO USE THIS INFORMATION:** This is a summary and does NOT have all possible information about this product. This information does not assure that this product is safe, effective, or appropriate for you. This information is not individual medical advice and does not substitute for the advice of your health care professional. Always ask your health care professional for complete information about this product and your specific health needs.

#### **TIRZEPATIDE (WEIGHT LOSS) - COMPOUNDED INJECTION** (tir-ZEP-a-tide)

**What is compounded tirzepatide?** Tirzepatide is a type of medication called a glucagon-like peptide 1 (GLP-1) receptor agonist, or "GLP-1" for short, used for the treatment of obesity and diabetes. Drug compounding is the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. The compounded tirzepatide you have been prescribed uses the same active pharmaceutical ingredient as brand name forms of tirzepatide.

Compounded drugs are permitted to be prescribed under federal law, but are not FDA-approved and do not undergo safety, effectiveness, or manufacturing review by FDA.

**USES:** This compounded medication is used with a provider-approved exercise, behavior change, and reduced-calorie diet program to help you lose weight. It is used by people with obesity and people with overweight and weight-related medical problems. Losing weight and keeping it off can lessen the many health risks that come with obesity, including heart disease, diabetes, high blood pressure, and a shorter life. Tirzepatide is similar to a natural hormone in your body (incretin). It works by controlling your appetite.

**How does tirzepatide work?** Tirzepatide acts like a hormone your body naturally makes to regulate blood sugar and appetite. Like other GLP-1s, tirzepatide is believed to help with weight management by slowing down how quickly food leaves your stomach, making you feel full faster and satiated for longer; and talking directly to the part of your brain in charge of feeling full, helping you regulate how much you eat.

**How is compounded tirzepatide prescribed?** Compounded tirzepatide typically starts at a low dose that is gradually increased over time. The typical dosing schedule of compounded tirzepatide is:

Weeks 1–4: 2.5 mg once a week

Weeks 5–8: 5 mg once a week

Weeks 9–12: 7.5 mg once a week

Weeks 13–16: 10 mg once a week

Weeks 17–20: 12.5 mg once a week

Weeks 21–24: 15 mg once a week

Depending on your experience with side effects and weight loss, your provider may maintain your dose at 5 mg, 10 mg, or 15 mg for more than four weeks.

Follow the dosing instructions from your provider, as they may personalize your plan for your individual needs.

**What if you have a previous prescription?** In the event you happen to have a previous prescription for brand name tirzepatide or another GLP-1, such as semaglutide, do not take with compounded tirzepatide. Taking two or more of these medications together increases potentially severe side effects.

**How do I inject compounded tirzepatide?** Compounded tirzepatide is injected once a week using the supplied syringes and needles. You may inject into your abdomen (at least two inches away from your navel), upper thigh, or upper arm. Follow the instructions in your Treatment Plan or the printed instructions that came with your medication, and reach out to your healthcare team if you need more help. It may be used with or without food. The dosage is based on your medical condition and response to treatment. Your provider will start you on a low dose first to decrease your risk of gastrointestinal side effects, and gradually increase your dose.

**What are the side effects of compounded tirzepatide?** The most common side effects are typically mild and usually resolve after the first several weeks of treatment. These can include nausea, vomiting, diarrhea, constipation, abdominal pain, upset stomach, abdominal distension, reflux, headache, fatigue, and dizziness. Swelling, redness, and itchiness at

the injection site may occur. The FDA has issued its most serious warning (called a **BOXED WARNING**) that GLP-1 medications may be associated with a type of thyroid cancer called medullary thyroid carcinoma. So far, this side effect has primarily been seen in laboratory studies using rodents, so the risk to humans has not been determined. For a complete list of side effects, including the Boxed Warning and less common side effects like ileus, see the Side Effects section below or your Treatment Plan.

**WARNING:** Tirzepatide has been found to cause a certain type of thyroid tumor (thyroid C-cell tumors) in rats and mice. It is unknown if this medication can cause similar tumors in humans. Talk with your provider about the benefits and risks of treatment with this medication. This medication should not be used by people with a personal/family history of a certain type of cancer (medullary thyroid carcinoma) or by people with a certain inherited disease (Multiple Endocrine Neoplasia syndrome type 2 or MEN 2). While using this medication, tell your provider right away if you notice any signs or symptoms of thyroid tumors, including unusual growth or lump in the neck, difficulty swallowing, shortness of breath, or unusual/lasting hoarseness.

**HOW TO USE:** Read your Treatment Plan before you start using compounded tirzepatide and each time you get a refill. Learn all preparation and usage instructions. If you have questions, ask your provider or pharmacist.

Each combination of syringe and needle is meant to be used only once. **Do not reuse a needle or syringe.**

Refer to your Treatment Plan for detailed injection instructions and to see a video demonstrating the steps.

**When your medication arrives:** The medication must be stored in the prescription bottle it comes in and placed in your refrigerator as soon as you receive it. The packaging is designed to keep your medication within an appropriate temperature range. If you haven't refrigerated your medication within 2 days of it shipping, contact us at care@ro.co.

**How to store your medication:** Refrigerate your medication as soon as it arrives. Store the vial of medication in the prescription bottle it came in and keep in your refrigerator at 36°–46° F (2°–8° C), keeping the vial in the medication

bottle it came in. **Discard any unused medication 28 days after first using the vial, or when the expiration date has passed, whichever comes first.**

**When to take your dose** Administer one dose each week, on the same day each week, at any time of day, with or without food.

Follow your provider's instructions carefully. Before injecting each dose, clean the injection site with rubbing alcohol. Change the injection site each time to lessen injury under the skin. Do not inject in an area that is tender, bruised, red, hard, or has scars or stretch marks. Use this medication at the dosing schedule prescribed by your provider to get the most benefit from it.

To help you remember, use it on the same day and time each week. It may help to mark your calendar with a reminder. Carefully follow the meal plan and exercise program your provider has recommended.

**SIDE EFFECTS:** See also Warning section. Nausea, vomiting, stomach upset, diarrhea, tiredness, dizziness, or constipation may occur. Nausea usually lessens as you continue to use tirzepatide. If any of these effects last or get worse, tell your provider or pharmacist promptly. Remember that this medication has been prescribed because your

provider has judged that the benefit to you is greater than the risk of side effects. Many people using this medication do not have serious side effects. Vomiting/diarrhea that doesn't stop may result in dehydration. Contact your provider promptly if you notice any symptoms of dehydration, such as unusual dry mouth/thirst or dizziness/lightheadedness. Tell your provider right away if you have any serious side effects, including: signs of kidney problems (such as change in the amount of urine), vision changes (such as decreased/blurred vision), fast heartbeat, mental/mood changes (such as depression, thoughts of suicide), signs of low blood sugar (sudden sweating, shaking, fast heartbeat, hunger, blurred vision, dizziness, tingling hands/feet).

Get medical help right away if you have any serious side effects, such as nausea/vomiting that doesn't stop or severe stomach/abdominal pain.

A very serious allergic reaction to this drug is rare. However, get medical help right away if you notice any symptoms of a serious allergic reaction, including: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing.

This is not a complete list of possible side effects. If you notice other effects not listed above, contact your provider or pharmacist.

In the US - Call your provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088 or at [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**PRECAUTIONS:** See also Warning section. Before using tirzepatide, tell your provider or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your provider or pharmacist your medical history, especially of: kidney disease, gallbladder disease, disease of the pancreas (pancreatitis), a certain eye problem (diabetic retinopathy), mental/mood disorders (such as depression, thoughts of suicide), certain stomach/intestinal disorders (gastroparesis, problems digesting food).

If you have diabetes, this product may affect your blood sugar. Check your blood sugar regularly as directed and share the results with your provider. Tell your provider right away if you have symptoms of low blood sugar (see Side Effects section). Your provider may need to adjust your diabetes medication(s), exercise program, or diet. This drug may make you dizzy. Alcohol or marijuana (cannabis) can make you more dizzy. Do not drive, use machinery, or do anything that needs alertness until you can do it safely. Limit alcoholic beverages. Talk to your provider if you are using marijuana (cannabis). Before having surgery, tell your provider or dentist about all the products you use (including prescription drugs, nonprescription drugs, and herbal products).

Tell your provider if you are pregnant or plan to become

pregnant. You should not become pregnant while using tirzepatide and for 2 months after the last dose. Tirzepatide may harm an unborn baby. If you become pregnant, talk to your provider right away about the risks and benefits of this medication. It is unknown if this medication passes into breast milk. Consult your provider before breastfeeding.

**DRUG INTERACTIONS:** Drug interactions may change how your medications work or increase your risk for serious side effects. This document does not contain all possible drug interactions. Keep a list of all the products you use (including prescription/nonprescription drugs and herbal products) and share it with your provider and pharmacist. Do not start, stop, or change the dosage of any medicines without your provider's approval.

Do not use this medication with any other product that contains tirzepatide or other medications which are similar to this medication (such as exenatide, dulaglutide).

**Oral contraception** (birth control pills) has been shown to be less effective when taking tirzepatide. The decrease in oral contraception's effectiveness is strongest whenever you start a new tirzepatide dose and improves over time. If you're taking an oral contraceptive, you should either: switch to a non-oral contraceptive method (such as an IUD or implant), OR continue using your oral contraception AND add a barrier method of contraception (such as condoms). You'll need to make either of those changes for 4 weeks after first starting compounded tirzepatide, AND for 4 weeks after each dose increase.

**Oral anticoagulants** (also known as blood thinners, Warfarin, Coumadin, or Jantoven) may be less effective while taking compounded tirzepatide. If you are taking an oral anticoagulant for atrial fibrillation, a heart condition, or blood clots that increase the risk of stroke, its effects will need to be monitored closely by the provider who prescribed that medication.

**OVERDOSE:** If someone has overdosed and has serious symptoms such as passing out or trouble breathing, call 911. Otherwise, call a poison control center right away. US residents can call their local poison control center at 1-800-222-1222. Symptoms of overdose may include: severe nausea/vomiting.

**NOTES:** Do not share this medication with others. Keep all medical and lab appointments. Consult your provider for more details.

**MISSED DOSE:** If you miss a dose, use it as soon as you remember. If it has been more than 4 days since your missed dose, skip the missed dose. Use your next dose at the regular time. Do not double the dose to catch up. If you miss more than 2 doses in a row, ask your provider if you should restart the medication with a lower dose to reduce your chance of side effects.

**STORAGE: How to store your medication** Refrigerate your medication as soon as it arrives. Store the vial of medication in the prescription bottle it came in. Keep it in your refrigerator at 36°–46° F (2°–8° C). Discard any unused medication 28 days after first using the vial, or when the expiration date has passed, whichever comes first.

Do not freeze. Keep in the original container to protect from light. Keep all medications away from children and pets.

Do not flush medications down the toilet or pour them into a drain unless instructed to do so. Properly discard this product when it is expired or no longer needed. Consult your pharmacist or local waste disposal company.

Under certain circumstances, chemical degradation of drugs may occur. Please call 888-263-9902 with any questions.

Information last revised August 2024.

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This is a compounded injection medication that contains

## Tirzepatide

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Patient Drug Information