

TIRZEPATIDE 30 MG / 3 ML SOLUTION FOR INJECTION IN PRE-FILLED PEN

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again (or access it online via the hosted link provided by your supplier or healthcare provider).
- If you have any further questions, ask your doctor, pharmacist, or healthcare provider.
- This medicine has been supplied for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Report side effects online if applicable in your region.

1. What Tirzepatide is and what it is used for

Tirzepatide is a dual glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) receptor agonist studied and used for weight management in adults with obesity or overweight with weight-related conditions, and for improving glycemic control in adults with type 2 diabetes (often as adjunct to diet and exercise). It reduces appetite, slows gastric emptying, increases insulin secretion, and supports significant weight loss.

This pre-filled injector pen contains 30 mg of tirzepatide dissolved in 3 ml of solution (concentration: 10 mg/ml). It is supplied for research, investigational, or off-label use under strict medical supervision only. Tirzepatide (as Mounjaro® or Zepbound®) is approved in various countries for type 2 diabetes and chronic weight management, but this specific 30 mg/3 ml pen format may align with compounded or investigational presentations—use only as directed by a qualified healthcare professional.

2. What you need to know before you use Tirzepatide

Do not use Tirzepatide if:

- You are allergic to tirzepatide, benzyl alcohol, or any of the other ingredients in the solution.
- You or any family member has a history of medullary thyroid carcinoma (MTC) or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- You have a personal or family history of certain thyroid cancers.
- You have severe gastrointestinal disease (e.g., severe gastroparesis) or a history of pancreatitis.
- You are pregnant, planning pregnancy, or breastfeeding.
- You are under 18 years of age (or under 10 for certain approved indications).

Warnings and precautions

Talk to your doctor before using Tirzepatide if you have:

- History of pancreatitis, gallstones, or gallbladder disease.
- Kidney problems.
- Diabetic retinopathy or other eye issues.
- Depression, suicidal thoughts, or mental health conditions.
- Heart rate issues (tirzepatide can cause increases in heart rate).
- Known allergy or sensitivity to benzyl alcohol (a preservative in the formulation), which may cause local reactions or, rarely, more serious effects in sensitive individuals.

Rapid weight loss may lead to gallstones, electrolyte imbalances, muscle loss, or excess/loose skin. Monitor closely and discuss supportive measures (e.g., nutrition, hydration, exercise).

Other medicines and Tirzepatide

Tell your doctor if you are taking: oral medications (absorption may be delayed), insulin, sulfonylureas or other diabetes medicines (increased risk of low blood sugar), or other weight-loss or GLP-1/GIP-based therapies.

Pregnancy and breast-feeding

Do not use if pregnant or breast-feeding. Use effective contraception during treatment and for a period after stopping (consult your doctor).

Driving and using machines

Tirzepatide may cause dizziness, fatigue, nausea, or low blood sugar (especially if combined with other glucose-lowering agents). Be cautious until you know how it affects you.

3. How to use Tirzepatide

Always use this medicine exactly as your doctor or healthcare provider has told you. Check with them if unsure.

This is a **pre-filled injector pen** containing 30 mg tirzepatide in 3 ml solution (10 mg/ml concentration). Administer as a **once-weekly subcutaneous injection**.

The pen uses a dial/click mechanism for precise dosing. Each click typically delivers 0.1 mg (based on common configurations for similar 10 mg/ml pens: 300 clicks total = 30 mg). Confirm your specific pen's calibration guide (included with the device or from your supplier/provider), as exact click-to-dose may vary slightly by design. A transparent window usually shows remaining volume.



Standard titration schedule (based on approved protocols for weight management/type 2 diabetes):

- **Weeks 1–4:** 2.5 mg (25 clicks)
- **Weeks 5–8:** 5 mg (50 clicks)
- **Weeks 9–12:** 7.5 mg (75 clicks) — if additional control needed and tolerated
- **Weeks 13–16:** 10 mg (100 clicks) — if needed
- **Weeks 17–20:** 12.5 mg (125 clicks) — if needed
- **Week 21 onward:** 15 mg (150 clicks) — maximum recommended dose

Maintenance & Limits

- Maintenance doses commonly range from 5 mg to 15 mg weekly, individualized based on response and tolerance.
- **Do not exceed 15 mg (150 clicks)** at any time. Higher doses are not recommended due to increased risks without proportional benefits.

How to inject:

- Inject subcutaneously (e.g., abdomen, thigh, or upper arm). Rotate injection sites each week.
- Inject on the same day and time each week (with or without food).
- Prime the pen if required (follow pen instructions). Dial/click to your dose, inject, and hold for a few seconds after injection.
- If you miss a dose: Administer as soon as possible if within 4 days (96 hours); otherwise, skip and resume on the next scheduled day. Do not double dose.

4. Possible side effects

Like all medicines, Tirzepatide can cause side effects, although not everybody gets them. Most are gastrointestinal, dose-related, and often improve with time or slower titration.

Very common (may affect more than 1 in 10 people):

- Nausea, vomiting, diarrhea, constipation, abdominal pain or discomfort.

Common:

- Decreased appetite, indigestion, fatigue, headache, dizziness, increased heart rate, injection site reactions (redness, itching, irritation)—may be influenced by the preservative benzyl alcohol in some individuals).

Serious (rare but seek immediate medical help):

- Severe persistent abdominal pain (possible pancreatitis or gallbladder issues).
- Signs of low blood sugar (shakiness, sweating, confusion—if combined with diabetes meds).
- Allergic reactions (rash, swelling, difficulty breathing—including potential reactions to benzyl alcohol).
- Gallbladder problems (upper abdominal pain, jaundice, fever).
- Mood changes or suicidal thoughts (rare—report immediately).
- Thyroid tumors (boxed warning: risk in animal studies; monitor for neck lumps/swelling).

In clinical trials, side effects were mostly mild to moderate, with higher incidence during escalation. Discontinuation rates varied but were generally low with gradual titration. Heart rate increases were observed but often transient.

Report any side effects to your doctor.

5. How to store Tirzepatide

- Store the pen in a refrigerator (2–8°C). Do not freeze.
- Protect from light and keep in the original packaging.
- If needed for short periods (e.g., travel), it may be stored at room temperature (below 30°C) for a limited time—check pen label or supplier instructions.
- Keep out of sight and reach of children.
- Do not use after the expiry date or if the solution appears cloudy, discolored, or contains particles. Dispose of used pens safely (follow local regulations for sharps disposal).

6. Contents of the pack and other information

What Tirzepatide contains:

- Active substance: Tirzepatide 30 mg in 3 ml solution (10 mg/ml).
- Other ingredients: Benzyl alcohol (preservative), and other excipients as per formulation (e.g., buffers, stabilizers—refer to pen label or supplier for the complete list).

Pack: Pre-filled injector pen (multi-dose design, total capacity 30 mg / 300 clicks at 0.1 mg per click).

Supplier / Hosting Note: This leaflet is hosted online for easy access and updates. Always refer to the latest version at the provided link. This is not a marketed product in this exact format; supplied for investigational/research use or compounded presentation.