

Patient Leaflet in Accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a physician's prescription only

Mounjaro

2.5 mg/0.5 ml

Solution for injection in a pre-filled pen

Mounjaro

5 mg/0.5 ml

Solution for injection in a pre-filled pen

Mounjaro

7.5 mg/0.5 ml

Solution for injection in a pre-filled pen

Mounjaro

10 mg/0.5 ml

Solution for injection in a pre-filled pen

Mounjaro

12.5 mg/0.5 ml

Solution for injection in a pre-filled pen

Mounjaro

15 mg/0.5 ml

Solution for injection in a pre-filled pen

The active ingredient and its concentration:

Each pre-filled pen contains 2.5 mg/ 5 mg/ 7.5 mg/ 10 mg/ 12.5 mg/ 15 mg Tirzepatide in 0.5 ml solution.

Inactive ingredients and allergens: see chapter 6 "Additional Information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information regarding this medicine. If you have any further questions, contact your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Mounjaro is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes.

Therapeutic group: drugs used in diabetes.

It is important to continue to follow the advice on diet and exercise given to you by your doctor, pharmacist or nurse.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are hypersensitive (allergic) to the active ingredient (tirzepatide) or any of the other ingredients of this medicine (listed in section 6).

Special warnings regarding the use of this medicine:

Before treatment with Mounjaro, talk to your doctor if:

- you have severe problems with food digestion or food remaining in your stomach for longer than normal (including severe gastroparesis).
- you have ever had pancreatitis (inflammation of the pancreas which may cause severe pain in the stomach and back which does not go away).
- you have a problem with your eyes (diabetic retinopathy or macular oedema).
- you are using a sulphonylurea (another diabetes medicine) or insulin for your diabetes, as low blood sugar (hypoglycaemia) can occur. Your doctor may need to change your dose of these other medicines to reduce this risk.

When starting treatment with **Mounjaro**, in some cases you may experience loss of fluids/dehydration, e.g. due to vomiting, nausea and/or diarrhea, which may lead to a decrease in kidney function. It is important to avoid dehydration by drinking plenty of fluids. Contact your doctor if you have any questions or concerns.

Children and adolescents

This medicine should not be given to children and adolescents under 18 years of age. There is no information regarding the safety and efficacy of use of this preparation in children and adolescents.

Drug interactions

If you are taking or have recently taken any other medicines, including nonprescription medications and nutritional supplements, tell your doctor or pharmacist.

Pregnancy, Breast-feeding and Fertility

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. This medicine should not be used during pregnancy as the effects of this medicine on an unborn child are not known. Therefore, it is recommended to use contraception while using this medicine.

It is unknown whether tirzepatide passes into breast milk. A risk to newborns/infants cannot be ruled out. If you are breast-feeding or are planning to breast-feed, talk to your doctor before using this medicine. You and your doctor should decide if you should stop breast-feeding or delay using **Mounjaro**.

Driving and using machines

Mounjaro has no or negligible influence on the ability to drive or use machines. However, if you use **Mounjaro** in combination with a sulphonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar, e.g. headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating (see section 4). See section 2, 'Before Using This Medicine' for information on increased risk of low blood sugar. Talk to your doctor for further information.

Important information about some of the ingredients of this medicine

Mounjaro contains sodium.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. HOW TO USE THIS MEDICINE?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about the dosage and manner of treatment with this medicine. The dosage and manner of treatment will be determined only by your doctor.

The usual dose is:

- The starting dose is 2.5 mg once a week for four weeks. After four weeks your doctor will increase your dose to 5 mg once a week.
- Your doctor may increase your dose by 2.5 mg increments to 7.5 mg, 10 mg, 12.5 mg or 15 mg once a week if you need it. In each case your doctor will tell you to stay on a particular dose for at least 4 weeks before going to a higher dose.

Do not change your dose unless your doctor has told you to.

Do not exceed the recommended dose.

Choosing when to give Mounjaro

Each pen contains one dose of **Mounjaro** either 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg.

You can use your pen at any time of the day, with or without meals. You should use it on the same day each week if you can. To help you remember when to use **Mounjaro**, you may wish to tick the day of the week when you inject your first dose on the box that your pen comes in or mark it on a calendar.

If necessary, you can change the day of your weekly **Mounjaro** injection, as long as it has been at least 3 days since your last injection. After selecting a new dosing day, continue with once-a-week dosing on that new day.

How to inject Mounjaro

Mounjaro is injected under the skin (subcutaneous injection) of your stomach area (abdomen) or upper leg (thigh) or upper arm. You may need help from someone else if you want to inject in your upper arm.

If you want to do so, you can use the same area of your body each week. But be sure to choose a different injection site within that area. If you also inject insulin choose a different injection site for that injection.

Testing blood glucose levels

If you are using **Mounjaro** with a sulphonylurea or insulin, it is important that you test your blood glucose levels as instructed by your doctor, pharmacist or nurse (see section 2, 'Before Using This Medicine').

Read the "Instructions for Use" for the pen carefully before using **Mounjaro**.

If you use more Mounjaro than you should

If you use more **Mounjaro** than you should talk to your doctor immediately. Too much of this medicine may cause low blood sugar (hypoglycaemia) and can make you feel sick or be sick.

If you have taken an overdose or if a child has accidentally swallowed the medicine, contact a doctor or a hospital Emergency Room immediately and bring the medicine package with you.

If you forget to use Mounjaro

If you forget to inject a dose and -

- it has been **4 days or less** since you should have used **Mounjaro**, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.
- If it has been **more than 4 days** since you should have used **Mounjaro**, skip the missed dose. Then inject your next dose as usual on your scheduled day.

Do not use a double dose of **Mounjaro** to make up for a forgotten dose. The minimum time between two doses must be at least 3 days.

If you stop using Mounjaro

Do not stop using **Mounjaro** without talking with your doctor. If you stop using **Mounjaro**, your blood sugar levels can increase.

Persist with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not discontinue treatment with this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult a doctor, pharmacist or nurse.

4. SIDE EFFECTS

Like all medicines, **Mounjaro** can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them.

Serious side effects

Uncommon side effects (may affect up to 1 in 100 people)

- Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away. You should see a doctor immediately if you experience such symptoms.

Other side effects

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

- Feeling sick (nausea)
- Diarrhea

These side effects are usually not severe. They are most common when first starting tirzepatide but decrease over time in most patients.

- Low blood sugar (hypoglycaemia) is very common when tirzepatide is used with medicines that contain a sulphonylurea and/or insulin. If you are using a sulphonylurea or insulin, the dose may need to be lowered while you use tirzepatide (see section 2, 'Before Using This Medicine'). Symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating. Your doctor should tell you how to treat low blood sugar.

Common side effects (may affect up to 1 in 10 people)

- Low blood sugar (hypoglycaemia) is common when tirzepatide is used with both metformin and a sodium-glucose co-transporter 2 inhibitor (another diabetes medicine)
- Allergic reaction (hypersensitivity) (e.g., rash, itching, and eczema)
- Feeling less hungry (decreased appetite)
- Stomach (abdominal) pain
- Being sick (vomiting) – this usually goes away over time
- Indigestion (dyspepsia)
- Constipation
- Bloating of the stomach
- Burping (eructation)
- Gas (flatulence)
- Reflux or heartburn (also called gastroesophageal reflux disease – GERD) - a disease caused by stomach acid coming up into the tube from your stomach to your mouth
- Feeling tired (fatigue)
- Injection site reactions (e.g. itching or redness)
- Fast pulse
- Increased levels of pancreatic enzymes (such as lipase and amylase) in blood.

Uncommon side effects (may affect up to 1 in 100 people)

- Low blood sugar (hypoglycaemia) is uncommon when tirzepatide is used with metformin.
- Gallstones
- Weight loss
- Increased calcitonin levels in blood.

If any of the side effects appears, if any of the side effects gets worse or if you experience a side effect not listed in this leaflet, talk to your doctor.

Reporting Side Effects

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects due to Drug Treatment” that can be found on the Home Page of the Ministry of Health’s website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THIS MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the label and package. The expiry date refers to the last day of that month.

Storage conditions:

Store in a refrigerator (2°C – 8°C).

Do not freeze. If the pen has been frozen, **do not use**.

Store in the original packaging in order to protect from light.

Mounjaro can be stored unrefrigerated not above 30°C for up to 21 cumulative days. If the medicine has been left out of the refrigerator for more than 21 days, it must be discarded, even if the expiration date has not yet expired.

Do not use this medicine if you notice that the pen is damaged, or the medicine is cloudy, discoloured or has particles in it.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, this medicine also contains:

Sodium chloride, dibasic sodium phosphate heptahydrate, water for injection. Hydrochloric acid solution and/or sodium hydroxide solution may have been added to adjust the pH.

What the medicine looks like and contents of the pack:

Mounjaro is a clear to opalescent solution, colorless to slightly yellow or brown, essentially free of particles.

Each pre-filled pen contains 0.5 ml solution.

The pre-filled pen has a hidden needle which will automatically insert into the skin when the injection button is pressed. The pre-filled pen will retract the needle when the injection is completed.

The pre-filled pen is for single-use only.

Each pack contains 4 pre-filled pens.

Registration holder’s name and address: Eli Lilly Israel Ltd., 4 HaSheizaf St., P.O.Box 4246, Ra’anana 4366411.

Manufacturer’s name and address: Eli Lilly & Company, Indianapolis, Indiana, USA.

Approved in April 2023 according to MOH guidelines.

Drug registration numbers at the national medicine’s registry of the Ministry of Health:

Mounjaro 2.5 mg/0.5 ml: 172-28-37425-00

Mounjaro 5 mg/0.5 ml: 172-29-37426-00

Mounjaro 7.5 mg/0.5 ml: 172-30-37427-00

Mounjaro 10 mg/0.5 ml: 172-31-37428-00
Mounjaro 12.5 mg/0.5 ml: 172-32-37429-00
Mounjaro 15 mg/0.5 ml: 172-33-37430-00

Instructions for Use

Important information you need to know before injecting Mounjaro

Read this instructions for use and the package leaflet before using your Mounjaro pre-filled pen (pen) and each time you get a new pen. There may be new information. This information does not take the place of talking to your doctor, pharmacist or nurse about your medical condition or treatment.



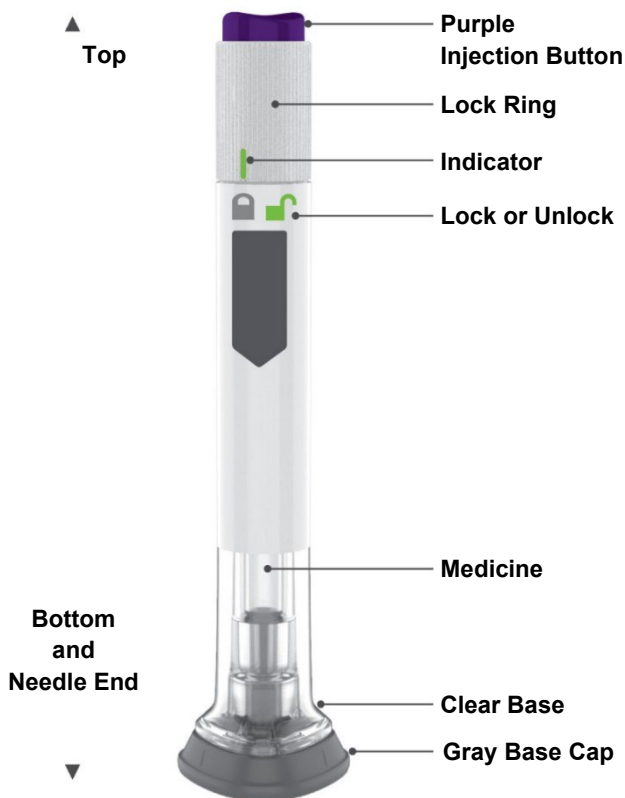
Talk to your doctor, pharmacist or nurse about how to inject **Mounjaro** the right way.

- **Mounjaro** is a single-dose pre-filled pen.
- The pen has a hidden needle which will automatically insert into your skin when the injection button is pressed. The pen will retract the needle when the injection is completed.
- **Mounjaro** is used 1 time each week.
- Inject under the skin (subcutaneously) only.
- You or another person can inject into your stomach (abdomen), upper leg (thigh) or upper arm.
- You may need help from someone else if you want to inject in your upper arm.

Storage and handling

- For storage instructions refer to section 5 of the patient information leaflet.
- The pen has glass parts. Handle it carefully. If you drop the pen on a hard surface, **do not use it**. Use a new pen for your injection.

Guide to parts

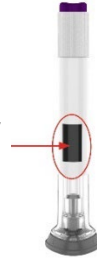


Preparing to inject Mounjaro

Remove the pen from the refrigerator.
Leave the grey base cap on until you are ready to inject.

Check the pen label to make sure you have the right medicine and dose, and that it has not expired.

Expiry
Date



Inspect the pen to make sure that it is not damaged.

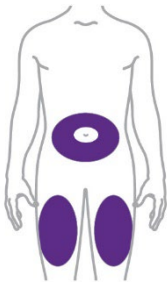
Make sure the medicine is:

- not frozen
- not cloudy
- clear and not discolored
- does not have particles

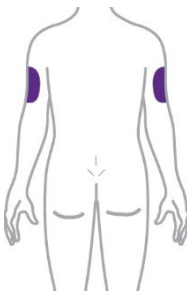
Wash your hands.

Choose your injection site

Your doctor can help you choose the injection site that is best for you.



You or another person can inject the medicine in your stomach (abdomen) or thigh.



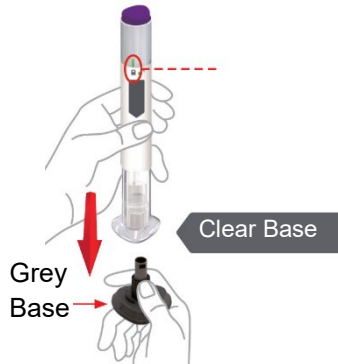
Another person should give you the injection in the back of your upper arm.

Change (rotate) your injection site each week.

You may use the same area of your body, but be sure to choose a different injection site in that area.

Step 1 Pull off the grey base cap

Make sure the pen is **locked**.



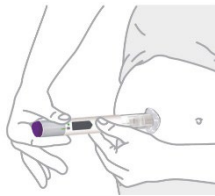
Do not unlock the pen until you place the clear base on your skin and are ready to inject.

Pull the grey base cap straight off and throw it away.

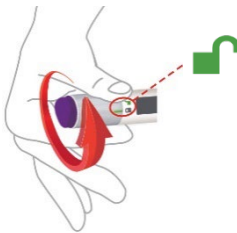
Do not put the grey base cap back on – this could damage the needle.

Do not touch the needle.

Step 2 Place clear base on skin, then unlock



Place the clear base flat against your skin at the injection site.



Unlock by turning the lock ring.

Step 3 Press and hold up to 10 seconds

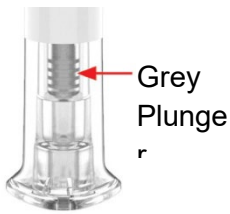


Press and hold the purple injection button.

Listen for:

- First click = injection started
- Second click = injection completed

You will know your injection is complete when the grey plunger is visible.



After your injection, place the used pen in a sharps container.

Disposal of your used pen

- Throw away (dispose of) the pen in a sharps container or as directed by your doctor, pharmacist or nurse. **Do not** throw away (dispose of) pens in your household waste.
- Do not recycle your used sharps disposal container.
- Ask your doctor, pharmacist or nurse about how to dispose of medicines you no longer use.



Commonly asked questions

What if I see air bubbles in my pen?

Air bubbles are normal.

What if my pen is not at room temperature?

It is not necessary to warm the pen to room temperature.

What if I unlock the pen and press the purple injection button before pulling off the grey base cap?

Do not remove the grey base cap. Throw away the pen and get a new pen.

What if there is a drop of liquid on the tip of the needle when I remove the grey base cap?

A drop of liquid on the tip of the needle is normal. **Do not** touch the needle.

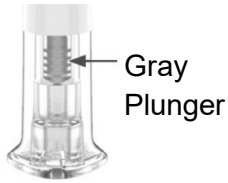
Do I need to hold the injection button down until the injection is complete?

This is not necessary, but it may help you keep the pen steady against your skin.

I heard more than 2 clicks during my injection — 2 loud clicks and 1 soft one. Did I get my complete injection?

Some people may hear a soft click right before the second loud click. That is the normal operation of the pen. **Do not** remove the pen from your skin until you hear the second loud click.

I am not sure if my pen worked the right way.



Check to see if you have received your dose. Your dose was delivered the right way if the gray plunger is visible. Also, see **Step 3** of the instructions.

If you do not see the gray plunger, contact Eli Lilly Israel Ltd. for further instructions. Until then, store your pen safely to avoid an accidental needle injury.

What if there is a drop of liquid or blood on my skin after my injection?

This is normal. Press a cotton ball or gauze over the injection site. **Do not** rub the injection site.

Other information

- If you have vision problems, **do not** use your pen without help from a person trained to use the **Mounjaro** pen.

Where to learn more

- If you have questions or problems with your Mounjaro pen, contact your doctor, pharmacist or nurse.

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