

# Getting started with Mounjaro<sup>®</sup> (Tirzepatide)

**Mounjaro<sup>®</sup> 2.5 -  
15 mg/ml solution  
for single dose vial  
of Tirzepatide.**



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get.

**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.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

**The information contained in this leaflet has been sourced from [medicines.org.uk](https://www.medicines.org.uk). Last updated: April 2025.**

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# What Mounjaro® is and what it is used for

Mounjaro is a medicine that contains an active substance called tirzepatide.

Mounjaro is used to treat adults with type 2 diabetes mellitus by reducing the level of sugar in the body only when the levels of sugar are high.

Mounjaro is also used for weight loss and weight maintenance in adults. Mounjaro primarily works by regulating your appetite, giving you a sense of satiety ('fullness'), making you feel less hungry and experience less food cravings. This will help you eat less food and reduce your body weight.

Mounjaro® is used:

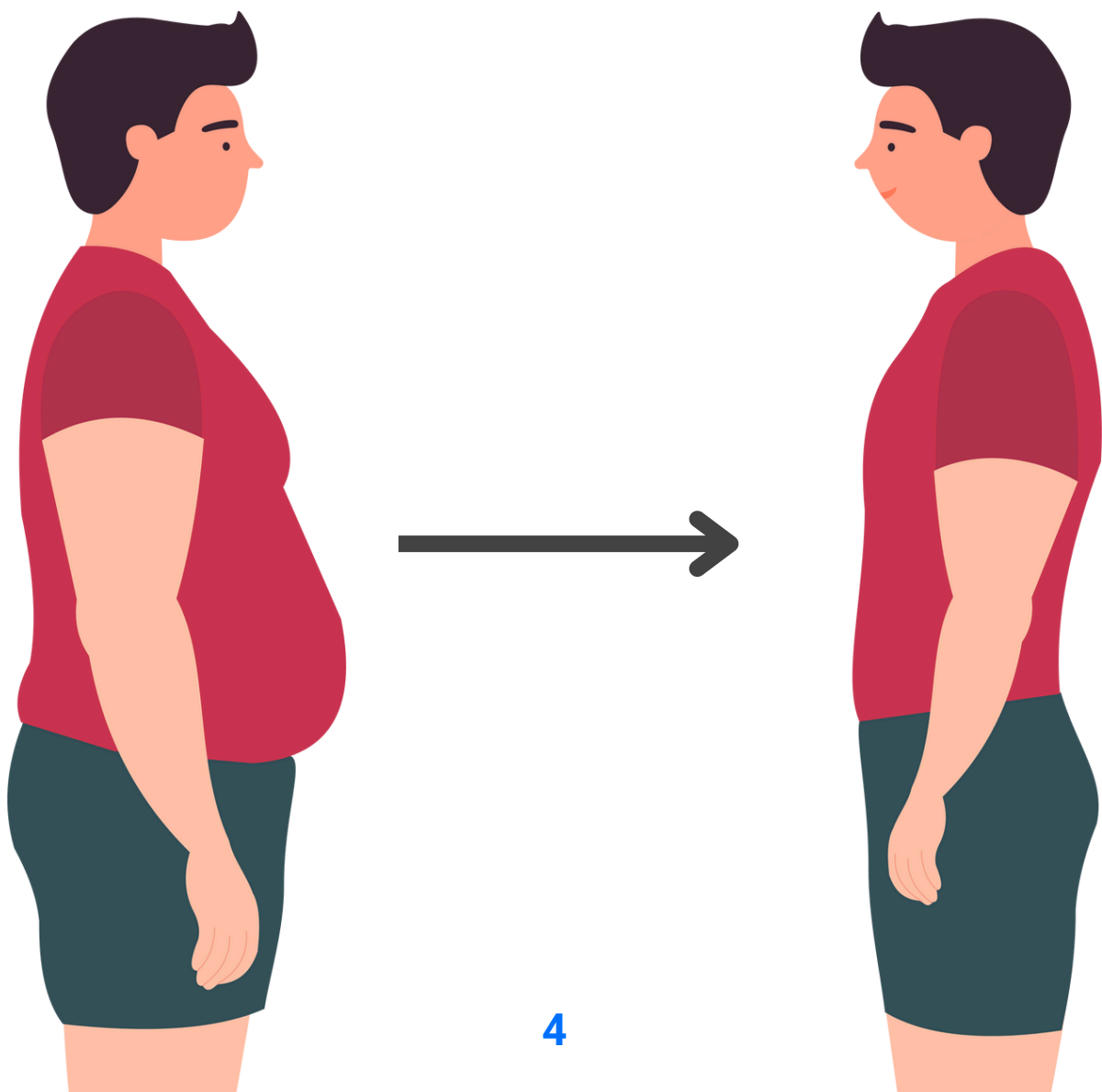
- On its own when you can't take metformin (another diabetes medicine).
- With other medicines for diabetes when they are not enough to control your blood sugar levels. These other medicines may be medicines taken by mouth and/or insulin given by injection

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

Mounjaro is also used together with reduced-calorie diet and increased physical activity for weight loss and to help keep the weight under control in adults, who have:

- A BMI of 30 kg/m<sup>2</sup> or greater (obesity) or
- A BMI of at least 27 kg/m<sup>2</sup> but less than 30 kg/m<sup>2</sup> (overweight) and weight-related health problems (such as prediabetes, type 2 diabetes, high blood pressure, abnormal levels of fats in the blood, breathing problems during sleep called 'obstructive sleep apnoea' or a history of heart attack, stroke or blood vessel problems)

BMI (Body Mass Index) is a measure of your weight in relation to your height.



# What you need to know before you use Mounjaro®

## Do not use Mounjaro®:

if you are allergic to tirzepatide or any of the other ingredients of this medicine

## Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Mounjaro® 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 diarrhoea, 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 because it has not been studied in this age group.

## **Other medicines and Mounjaro**

Tell your doctor, pharmacist or nurse if you are using, have recently used or might use any other medicines.

## **Pregnancy**

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.

If you are a woman with obesity or overweight and are using oral contraceptives, you should consider also using a barrier method of contraception (e.g., a condom) or switching to a non-oral contraceptive method for 4 weeks after starting Mounjaro and for 4 weeks after each increase in dose.

## **Breast-feeding**

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**

It is unlikely that this medicine will affect your ability to drive and 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, 'Warnings and precautions' for information on increased risk of low blood sugar. Talk to your doctor for further information.

## **Mounjaro® contains sodium**

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



## Surgery Endoscopy or Colonoscopy

If you are planning for any surgery under general anaesthesia or interventions like endoscopy or colonoscopy please inform your specialist that you are on this weight loss medication and hold off this medication 2 weeks before the surgery. Restart this medication one week after you are feeling better and back to your normal self. If you have any queries, please do not hesitate to contact us.

If you are having an emergency surgery or urgent procedure, please mention to the doctors involved in your care that you are on this weight loss medication.



# How to use Mounjaro®

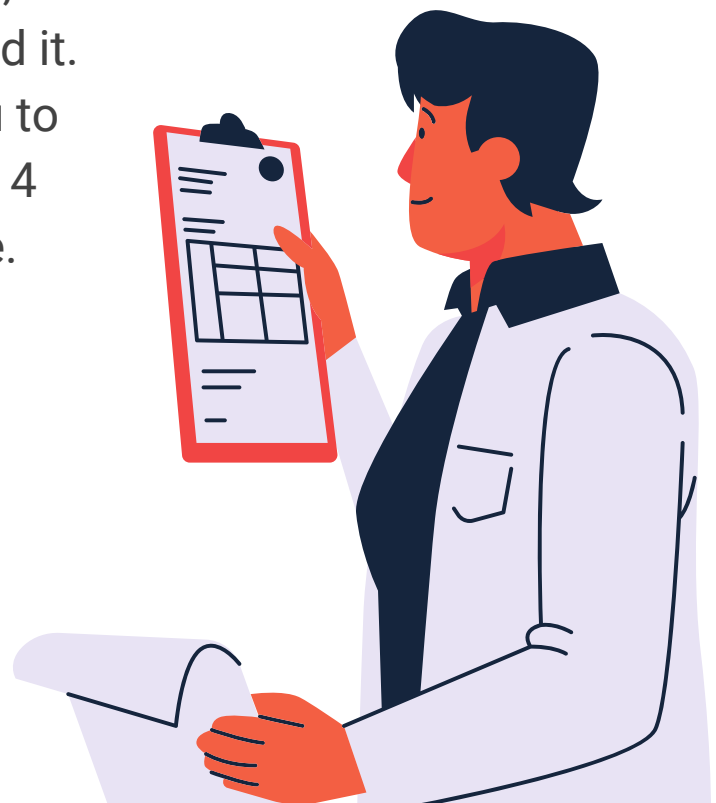
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Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure how to use this medicine.

## How much to use

- 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.



# Choosing when to give Mounjaro®

Each vial contains one dose of Mounjaro® either:



2.5 mg



5 mg



7.5 mg



10 mg



12.5 mg



15 mg

## Choosing when to give Mounjaro®

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.

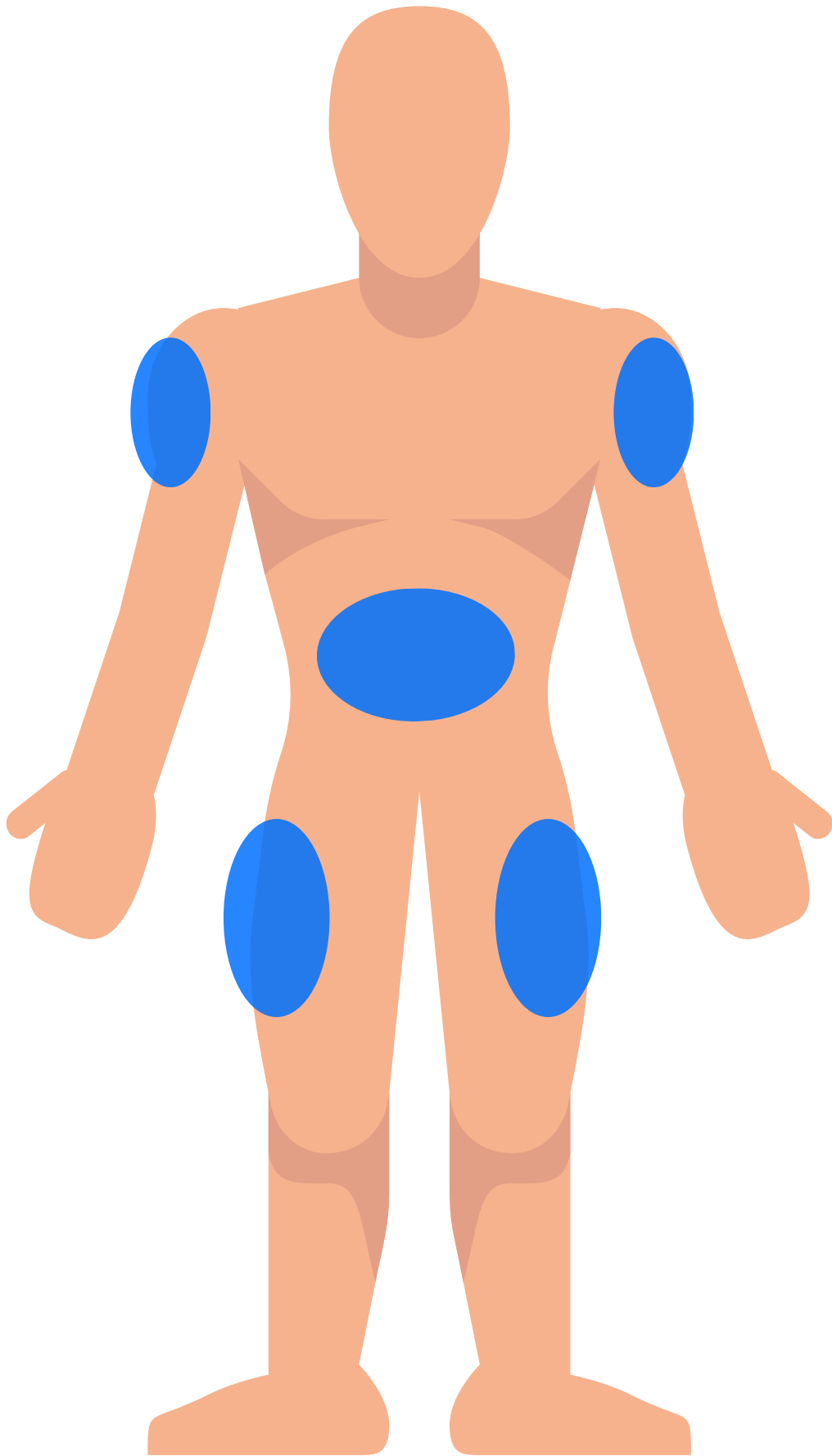
If necessary, you can change the day of your weekly Mounjaro® injection, as long as it has been at least 3 days since your last injection. After selecting a new dosing day, continue with once-a-week dosing on that new day.

## 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.

Read the “Instructions for Use” for the pen carefully before using Mounjaro®



## 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, 'Warnings and precautions').

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 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 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.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.



# Possible side effects of Mounjaro®

Like all medicines, this medicine can cause side effects, although not everybody gets them.

## Serious side effects

### Uncommon (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

### Rare (may affect up to 1 in 1000 people)

- Severe allergic reactions (e.g. anaphylactic reaction, angioedema). You should get immediate medical help and inform your doctor if you experience symptoms such as breathing problems, rapid swelling of the lips, tongue and/or throat with difficulty swallowing and a fast heartbeat.



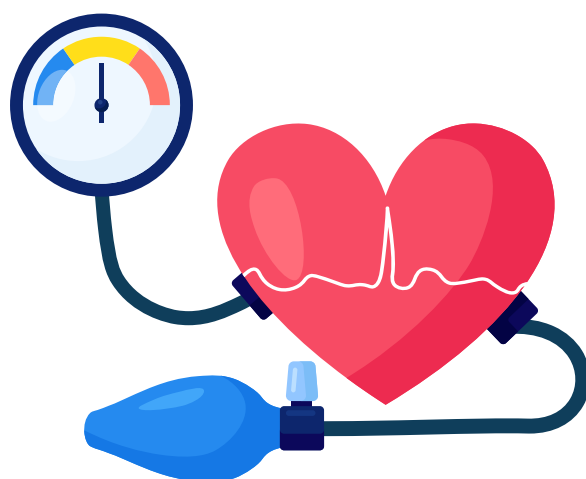
## Other side effects

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

- Low blood sugar (hypoglycaemia) when tirzepatide is used for the treatment of type 2 diabetes 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. 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.
- Feeling sick (nausea)\*
- Diarrhoea\*
- Being sick (vomiting) – this usually goes away over time\*\*
- Constipation\*\*.

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

\*\*Constipation and vomiting are very common when used for weight management, but common when used for type 2 diabetes.



**Common:** may affect up to 1 in 10 people

- Low blood sugar (hypoglycaemia) when tirzepatide is used for type 2 diabetes with both metformin and a sodium-glucose co-transporter 2 inhibitor (another diabetes 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.
- Allergic reaction (hypersensitivity) (e.g., rash, itching, and eczema)
- Dizziness observed in patients treated for weight management
- Low blood pressure observed in patients treated for weight management
- Feeling less hungry (decreased appetite) observed in patients treated for type 2 diabetes
- Stomach (abdominal) pain
- Indigestion (dyspepsia)
- Bloating of the stomach
- Burping (eructation)
- Gas (flatulence)
- Reflux or heartburn (also called gastroesophageal reflux disease – GORD) - a disease caused by stomach acid coming up into the tube from your stomach to your mouth
- Hair loss observed in patients treated for weight management
- 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

Fast pulse is a common side effect when used for type 2 diabetes and uncommon when used for weight management.

Increased levels of amylase is uncommon in weight management.

**Uncommon:** may affect up to 1 in 100 people

- Low blood sugar (hypoglycaemia) when tirzepatide is used with metformin for type 2 diabetes. 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.
- Gallstones
- Weight loss observed in patients treated for type 2 diabetes
- Injection site pain
- Increased calcitonin levels in blood
- Cholecystitis (infection of the gallbladder) observed in patients treated for weight management.

## Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

### United Kingdom

Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA

Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

# How to store Mounjaro®

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and on the carton after EXP. The expiry date refers to the last day of that month.

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 and then the pen must be discarded.

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.

# How to use Mounjaro®

## Preparing for your Mounjaro® injection

- **Wash** your hands with soap and water
- **Remove** the vial from the carton
- **Check** the vial label
- **Inspect** the vial to make sure it has not expired
- If the medicine is frozen, cloudy, or has particles in it, **do not use**, and contact your healthcare provider

## Remember

- **Always use a new syringe and needle for each injection** to prevent infections and blocked needles
- **Do not reuse or share your syringes or needles** with other people. You may give other people a serious infection or get a serious infection from them.

1



- Pull the plastic protective cap off the single-dose vial
- **Do not** remove the rubber stopper

2



- Wipe the rubber stopper with the alcohol swab

3

- Remove the outer wrapping from the syringe

4

**The syringe your doctor recommended might have a pre-attached needle. If so, go to step 6.**

- If the needle and syringe recommended by your doctor are separate, you will need to attach them
- Remove the outer wrapping from the needle

5

- Line the needle up with the syringe and keep it straight as you attach it
- Place the needle on top of the syringe and turn, or push it on until it is tight and firmly attached, as instructed by your healthcare provider

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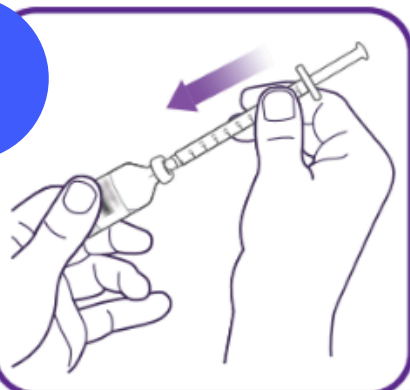
- Remove the needle shield by pulling it straight off
- Make sure that the needle does not touch any other surfaces

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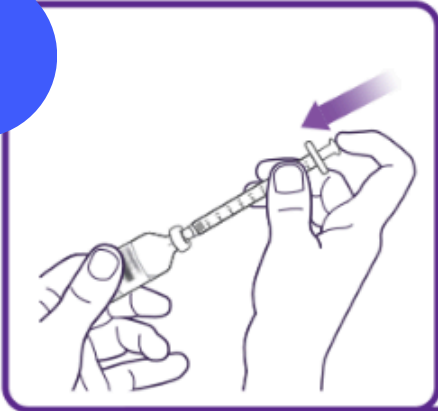
- Hold the syringe with the needle pointing up
- Pull down on the plunger until the plunger tip reaches the line on the syringe indicating that 0.5 mL of air has been drawn into the syringe

8



- Push the needle through the rubber stopper of the vial

9



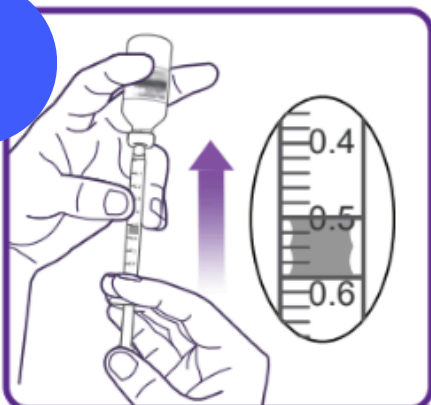
- Push the plunger all the way in
- This puts air into the vial, making it easier to pull the solution from the vial

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- Turn the vial and syringe upside down
- Make sure the tip of the needle is in the solution then slowly pull the plunger down until the plunger tip is past the 0.5 mL line
- If there are air bubbles, gently tap the syringe a few times to let any air bubbles rise to the top

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- Slowly push the plunger up until the plunger tip reaches the 0.5 mL line
- At this point, there should be no air in the syringe



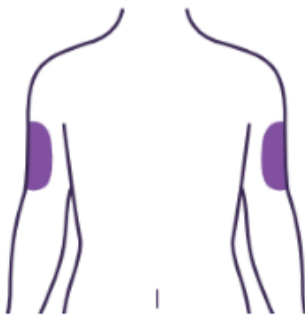
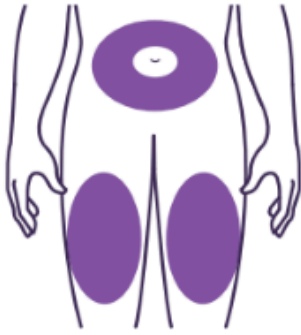
- Pull the syringe out of the rubber stopper of the vial
- Make sure to pull the syringe straight out to avoid bending the needle
- Make sure that the needle does not touch any other surfaces

## Injecting Mounjaro® single-dose vial

### Remember

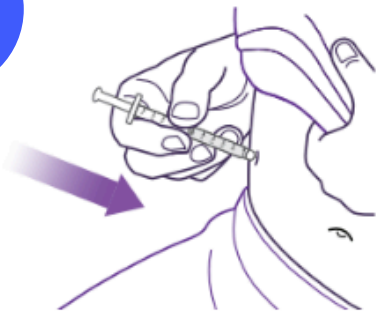
- **Inject exactly as your healthcare provider has shown you**
- Each week, **change (rotate) your injection site** within the area you choose for your dose to reduce your risk of developing pits in the skin, thickened skin, or skin with lumps at the injection site
- **Do not** inject where the skin has pits, is thickened, or has lumps
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin
- **Do not** mix Mounjaro® with any other medicine
- **Do not** inject Mounjaro® in the same injection site used for other medicines

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- **Prepare the injection site** as directed by your healthcare provider
- Mounjaro® is injected under the skin (subcutaneously)
- You or another person can inject the medicine in your **stomach area** (abdomen) or **thigh**
- Or someone else can give you the injection in the **back of your upper arm**

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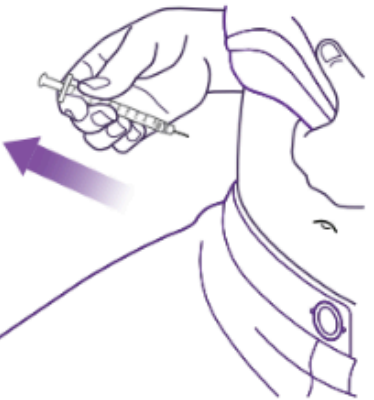
- Insert the needle into your skin

15



- Push down on the plunger to inject your full dose
- The plunger tip should be pushed to the bottom of the syringe
- The needle should stay in your skin for at least 5 seconds to make sure you have injected all of your medicine

16



- Pull the needle out of your skin
- If you see blood after you remove the needle, press the injection site with a piece of gauze or an alcohol swab. **Do not** rub the area.
- **Do not** recap the needle as this could lead to a needle stick injury

## Disposing of used needles and syringes

- Put your used needle and syringe in a sharps disposal container
- **Do not throw away needles or syringes in your household trash**
- If you do not have a sharps disposal container, refer to the Instructions for Use that came with your medication
- **Do not recycle your used sharps disposal container**
- **Keep your sharps disposal container out of the sight and reach of children**

## Disposing of used vials

- Throw away all opened vials after use, even if there is medicine left in the vial
- Put your used vial in your household trash
- **Do not recycle used vials or put them in a sharps disposal container**



# Contents of the pack and other information

## What Mounjaro® contains

The active substance is tirzepatide.

- Mounjaro® 2.5 mg: Each single dose vial contains 2.5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro® 5 mg: Each single dose vial contains 5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro® 7.5 mg: Each single dose vial contains 7.5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro® 10 mg: Each single dose vial contains 10 mg of tirzepatide in 0.5 ml solution.
- Mounjaro® 12.5 mg: Each single dose vial contains 12.5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro® 15 mg: Each single dose vial contains 15 mg of tirzepatide in 0.5 ml solution.

The other ingredients are sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide (see section under 'Mounjaro® contains sodium' for further information); concentrated hydrochloric acid and water for injections.

### **What Mounjaro® looks like and contents of the pack**

Mounjaro® is a clear, colourless to slightly yellow, sterile, preservative-free solution for subcutaneous use. Each single-dose vial contains a 0.5 mL solution of 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg of Tirzepatide and the following excipients: sodium chloride (4.1 mg), sodium phosphate dibasic heptahydrate (0.7 mg), and water for injection. Hydrochloric acid solution and/or sodium hydroxide solution may have been added to adjust the pH. Mounjaro® has a pH of 6.5 – 7.5.

### **Manufacturer:**

M/s. Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, Indiana 46285 USA

### **Imported by:**

M/s. Eli Lilly and Company (India) Pvt. Ltd.  
Gala No. 203, Bldg. No. G-3,  
Second floor, H. No. 986,  
Bhumi World Industrial Park Pimplas,  
Bhiwandi, Dist. Thane - 421302

## Marketed by:

\*Eli Lilly and Company (India) Pvt. Ltd.

Plot No. 92, Sector-32, Gurgaon-122001, Haryana, India

[www.lillyindia.co.in](http://www.lillyindia.co.in)

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If you have any questions or complaints with your MOUNJARO®, contact Lilly at Toll Free number

18001230021 or your healthcare professional for assistance.

## DETAILS OF PERMISSION

**IMP/SND/24/000059** dated 18-Sep-2024 (MA Permission number)

**The information contained in this leaflet has been sourced from [medicines.org.uk](http://medicines.org.uk). Last updated: April 2025.**

