

Package leaflet: Information for the patient

Mounjaro® 2.5 mg solution for injection in vial

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. See the end of section 4 for how to report side effects.

The name of your medicine is Mounjaro 2.5 mg solution for injection in vial but will be referred to as Mounjaro throughout this leaflet. Please note that the leaflet also contains information about other strengths.

**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. See section 4.

What is in this leaflet

1. What Mounjaro is and what it is used for
2. What you need to know before you use Mounjaro
3. How to use Mounjaro
4. Possible side effects
5. How to store Mounjaro
6. Contents of the pack and other information

1. What Mounjaro is and what it is used for

What Mounjaro is

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.

What Mounjaro is used for

In type 2 diabetes, 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/m² or greater (obesity) or
- a BMI of at least 27 kg/m² but less than 30 kg/m² (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.

2. 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 (listed in section 6).

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

This medicine should not be used during pregnancy as the effects of this medicine on an unborn child are not known. 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. 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 section 4). See section 2, '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'.

3. How to use Mounjaro

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

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

You can use Mounjaro 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 mark on a calendar the day of the week when you inject your first dose.

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

If you are injecting this medicine yourself, you will be shown how to prepare and inject the medicine by your doctor, pharmacist or nurse. Do not inject this medicine yourself unless you have received training and you understand the procedure.

Always use Mounjaro exactly as your doctor has told you. Before you begin using Mounjaro, always read the "Instructions for Use" below carefully, and talk to your doctor, pharmacist or nurse if you are not sure about how to inject Mounjaro correctly.

If you experience any issues with self-administration, seek medical attention.

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. **Do not** inject Mounjaro directly into a vein, as this will change its action.

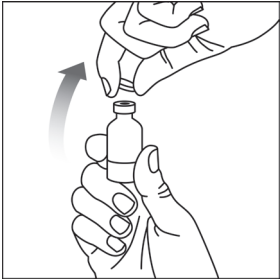
If you want to do so, you can use the same area of your body each week. But be sure to choose a different injection site within that area. If you also inject insulin choose a different injection site for that injection. If you are blind or visually impaired, you will need help from someone to make your injection.

Read the "Instructions for Use" below carefully before using Mounjaro.

**Step 1** First wash your hands with soap and water.

**Step 2** Check that the Mounjaro in the vial looks clear and colourless to slightly yellow.  
**Do not** use if it is frozen, cloudy, or has particles in it.

**Step 3** Pull off the vial plastic protective cap, but **do not** remove the stopper.

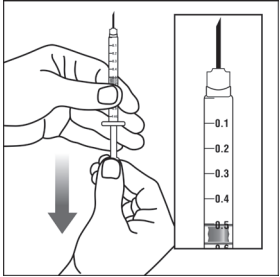


**Step 4** Clean the stopper on the vial with a swab.

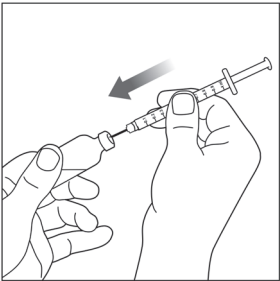
**Step 5** Prepare a new syringe and needle.  
Use a suitable syringe that has a marking of 0.5ml. It is recommended to use a 29 to 33 Gauge needle, with a length of 4 to 8mm.

**Do not share or reuse your needle or syringe.**

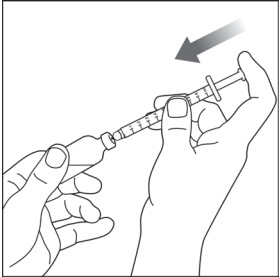
**Step 6** Hold the syringe in one hand with the needle pointing up. With the other hand pull down on the plunger until the plunger tip reaches the line on the syringe indicating that 0.5 mL of air has been drawn into the syringe.



**Step 7** Put the needle through the rubber stopper on top of the Mounjaro vial.

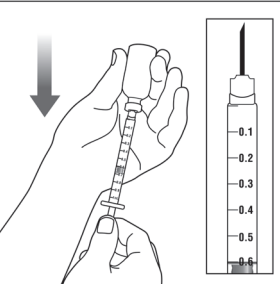


**Step 8** Inject all the air into the vial.



**Step 9** Turn the Mounjaro vial and the syringe upside down, making sure the tip of the needle is in the solution. Slowly pull the syringe plunger down to withdraw 0.5 ml of Mounjaro solution from the vial. The vial is filled to enable delivery of a single 0.5 ml dose of Mounjaro.

If there are air bubbles in the syringe, tap the syringe gently a few times to let any air bubbles rise to the top. Slowly push the plunger up until there is no more air in the syringe.

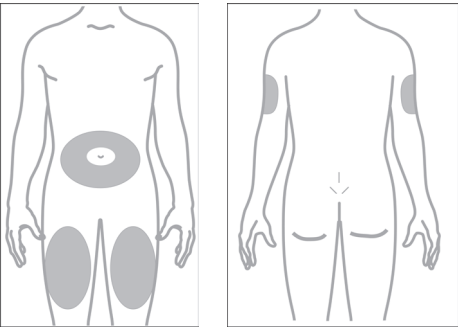


**Step 10** Once you have 0.5 ml solution in the syringe with no air bubbles, pull the syringe out of the vial stopper.

**Step 11** Choose your injection site. Mounjaro can be injected under the skin (subcutaneously) of your stomach area (abdomen) or thighs, and with the help of someone else, in the back of the upper arm.

Ensure the area of skin you wish to inject into is clean. If it is not, clean with soap and water and allow to dry.

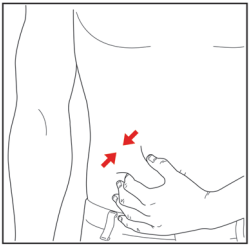
Change (rotate) your injection site within the area you choose for each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.



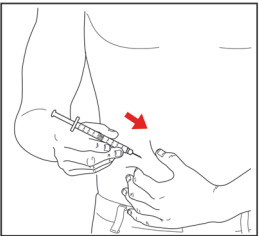
- **Do not** inject where the skin has pits, is thickened, or has lumps.
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Do not** mix Mounjaro with any other medicine.
- **Do not** inject Mounjaro in the same injection site used for other medicines.

**Step 12** Gently pinch and hold a fold of skin where you will inject between your thumb and forefinger.

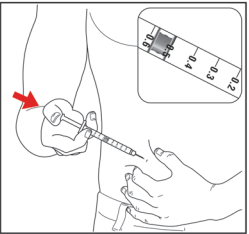
The lifted skin fold should not be squeezed so tightly that it causes pain or skin blanching (when skin goes white or pale when pressed).



**Step 13** Insert the needle into your skin.



**Step 14** Inject under the skin, as you have been instructed. Inject all the solution from the syringe to receive a full dose. After your injection, the needle should stay under your skin for 5 seconds to make sure you receive the full dose.



**Step 15** Pull the needle out of your skin. Release the skin fold, if you see blood after you take the needle out of your skin, press the injection site with a piece of gauze.  
**Do not** rub the area.

**Step 16** Throw away the vial, used needle and syringe immediately after each injection in a puncture resistant container, or as instructed by your doctor, pharmacist or nurse.

**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').

**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, and you have type 2 diabetes, your blood sugar levels can increase.

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

**4. Possible side effects**

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 1 000 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 (see section 2, 'Warnings and precautions'). 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<sup>1</sup>
  - Increased levels of pancreatic enzymes (such as lipase and amylase<sup>2</sup>) in blood.

<sup>1</sup>Fast pulse is a common side effect when used for type 2 diabetes and uncommon when used for weight management.

<sup>2</sup>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
- Changed sense of taste.

**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 the 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.

**5. 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 vial 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 vial 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 vial must be discarded.

Do not use this medicine if you notice that the vial, seal or stopper is damaged, or the medicine is cloudy, discoloured or has particles in it. If this medicine becomes discoloured or shows any other signs of deterioration, please contact your pharmacist who will advise you on what to do.

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. Contents of the pack and other information**

**What Mounjaro contains**

- The active substance is tirzepatide.
- *Mounjaro 2.5 mg*: Each vial contains 2.5 mg of tirzepatide in 0.5 ml solution.

The other ingredients are sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide (see section 2 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, solution for injection in a vial.

The vial is for single use only.

Pack contains one vial.

Needles and syringe are not provided in this pack.

**Product Licence Holder and Manufacturer**

Procured from within the EU by the Product Licence holder Orifarm UK Ltd., Ground Floor Suite A2, Breakspear Park, Breakspear Way, Hemel Hempstead, HP2 4 TZ, UK

For any information about this medicine, please contact the Product Licence Holder on [www.orifarm.com/uk](http://www.orifarm.com/uk)  
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**PLGB 45985/0904**

**POM**

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