

Package leaflet: Information for the patient

Mounjaro[®] 2.5 mg solution for injection in pre-filled pen
Mounjaro[®] 5 mg solution for injection in pre-filled pen
Mounjaro[®] 7.5 mg solution for injection in pre-filled pen
Mounjaro[®] 10 mg solution for injection in pre-filled pen
Mounjaro[®] 12.5 mg solution for injection in pre-filled pen
Mounjaro[®] 15 mg solution for injection in pre-filled pen
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.

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, nurse or pharmacist.
- 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, nurse or pharmacist. 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
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1. What Mounjaro is and what it is used for

Mounjaro contains an active substance called tirzepatide and is used to treat adults with type 2 diabetes mellitus. Mounjaro reduces the level of sugar in the body only when the levels of sugar are high.

Mounjaro is also used to treat adults with obesity or overweight (with BMI of at least 27 kg/m²). Mounjaro influences appetite regulation, which may help you eat less food and reduce your body weight.

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.

Mounjaro is also used together with diet and exercise 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.

In patients with obstructive sleep apnoea (OSA) and obesity, Mounjaro can be used with or without positive airway pressure (PAP) therapy.

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

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, nurse or pharmacist 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.

If you know that you are due to have surgery where you will be under anaesthesia (sleeping), please tell your doctor that you are taking Mounjaro.

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, nurse or pharmacist 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.

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

- 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.

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

Choosing when to use 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) at least 5 cm from the belly button 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, nurse or pharmacist (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, nurse or pharmacist.

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)

- Feeling sick (nausea)
- Diarrhoea
- Stomach (abdominal) pain reported in patients treated for weight management
- Being sick (vomiting) reported in patients treated for weight management
- Constipation reported in patients treated for weight management

These side effects are usually not severe. Nausea, diarrhoea, and vomiting 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 for type 2 diabetes, 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.

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)
- Allergic reaction (hypersensitivity) (e.g., rash, itching, and eczema)

- Dizziness reported in patients treated for weight management
- Low blood pressure reported in patients treated for weight management
- Feeling less hungry (decreased appetite) reported in patients treated for type 2 diabetes
- Stomach (abdominal) pain reported in patients treated for type 2 diabetes
- Being sick (vomiting) reported in patients treated for type 2 diabetes - this usually decreases over time
- Indigestion (dyspepsia)
- Constipation reported in patients treated for type 2 diabetes
- 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
- Hair loss reported 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
- Increased calcitonin levels in blood in patients treated for 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.
- Gallstones
- Inflammation of the gallbladder
- Weight loss reported in patients treated for type 2 diabetes
- Injection site pain
- Increased calcitonin levels in blood in patients treated for type 2 diabetes or for OSA with obesity
- Changed sense of taste

Reporting of side effects

If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via **Ireland**: HPRA Pharmacovigilance, website: www.hpra.ie. 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 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 below 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.

6. Contents of the pack and other information

What Mounjaro contains

The active substance is tirzepatide.

- *Mounjaro 2.5 mg*: Each pre-filled pen contains 2.5 mg of tirzepatide in 0.5 ml solution (5 mg/ml).
- *Mounjaro 5 mg*: Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution (10 mg/ml).
- *Mounjaro 7.5 mg*: Each pre-filled pen contains 7.5 mg of tirzepatide in 0.5 ml solution (15 mg/ml).
- *Mounjaro 10 mg*: Each pre-filled pen contains 10 mg of tirzepatide in 0.5 ml solution (20 mg/ml).
- *Mounjaro 12.5 mg*: Each pre-filled pen contains 12.5 mg of tirzepatide in 0.5 ml solution (25 mg/ml).
- *Mounjaro 15 mg*: Each pre-filled pen contains 15 mg of tirzepatide in 0.5 ml solution (30 mg/ml).

The other ingredients are disodium hydrogen phosphate heptahydrate (E339), 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 pre-filled pen.

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.

Each pre-filled pen contains 0.5 ml solution.

The pre-filled pen is for single use only.

Pack sizes of 2 pre-filled pens, 4 pre-filled pens or multipack of 12 (3 packs of 4) pre-filled pens. Not all pack sizes may be available in your country.

Marketing Authorisation Holder

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, The Netherlands.

Manufacturer

Eli Lilly Italia S.p.A., Via Gramsci 731/733, 50019, Sesto Fiorentino, Firenze (FI), Italy
Lilly France, 2, rue du Colonel Lilly, 67640 Fegersheim, France

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.

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