

MOUNJARO® vial

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using MOUNJARO?

MOUNJARO contains the active ingredient tirzepatide. In adults with type 2 diabetes, MOUNJARO is used to improve blood sugar control. In adults who are overweight or have obesity, MOUNJARO is used for weight management.

For more information, see Section [1. Why am I using MOUNJARO?](#) in the full CMI.

2. What should I know before I use MOUNJARO?

Do not use if you have ever had an allergic reaction to tirzepatide or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use MOUNJARO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MOUNJARO and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MOUNJARO?

- MOUNJARO is supplied as a single-use vial that is used once a week, **on the same day each week** if you can.
- When you first start using MOUNJARO, the starting dose is 2.5 mg once a week for 4 weeks. After 4 weeks your dose will be increased to 5 mg once a week.
- Your doctor may choose to increase your dose by 2.5 mg every 4 weeks to achieve a dose of 7.5 mg, 10 mg, 12.5 mg or 15 mg once a week if needed. The maximum dose is 15 mg once weekly.

More instructions can be found in Section [4. How do I use MOUNJARO?](#) in the full CMI.

5. What should I know while using MOUNJARO?

Things you should do	<ul style="list-style-type: none">● Remind any doctor, surgeon, anaesthetist, pharmacist, or nurse you visit that you are using MOUNJARO.● If you have diabetes, always carry glucose or sugary foods with you. Tell your doctor if you experience low blood sugar, called hypoglycaemia and this occurs often.
Things you should not do	<ul style="list-style-type: none">● Do not stop using this medicine suddenly and without consulting your Doctor/Healthcare provider.● Do not use this medicine if you think it has been frozen or exposed to excessive heat.
Driving or using machines	<ul style="list-style-type: none">● Be careful before you drive or use machines or tools until you know how MOUNJARO affects you.

	<ul style="list-style-type: none"> • Hypoglycaemia (low blood sugar) may affect your ability to concentrate.
Drinking alcohol	<ul style="list-style-type: none"> • Tell your doctor if you drink alcohol. Alcohol may mask the symptoms of hypoglycaemia (low blood sugar) or make it worse.
Looking after your medicine	<ul style="list-style-type: none"> • Store MOUNJARO in a refrigerator (2°C - 8°C). Do not freeze. • Keep MOUNJARO in the original package in order to protect from light until ready to use.

For more information, see Section [5. What should I know while using MOUNJARO?](#) in the full CMI.

6. Are there any side effects?

The most common side effects are nausea, diarrhoea, vomiting, abdominal (stomach) pain, and decreased appetite. These side effects are usually not severe. Serious side effects which may require urgent medical attention may include inflamed pancreas (acute pancreatitis - sudden severe pain in the stomach and back), gallbladder complaints and allergic reactions. For

more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring due to approval of an extension of indications. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

MOUNJARO® vial (muhn-JAHR-oh)

Active ingredient: *tirzepatide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MOUNJARO. **You should also speak to your doctor, pharmacist, or nurse if you would like further information or if you have any concerns or questions about using MOUNJARO.**

Where to find information in this leaflet:

- [1. Why am I using MOUNJARO?](#)
- [2. What should I know before I use MOUNJARO?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MOUNJARO?](#)
- [5. What should I know while using MOUNJARO?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MOUNJARO?

MOUNJARO contains the active ingredient tirzepatide. MOUNJARO is a type of medicine called 'GIP and GLP-1 receptor agonists'. In adults, this medicine is used to help treat diabetes. In adults who are overweight or have obesity, this medicine is used to reduce weight or maintain weight loss.

Type 2 Diabetes

Diabetes mellitus is a condition in which your pancreas does not produce enough insulin to control your blood sugar (glucose) level.

In adults with type 2 diabetes, MOUNJARO is used to improve blood sugar control. MOUNJARO may be used alone or in combination with other diabetes medicines to control your blood sugar levels.

Weight Management

In adults who are overweight or have obesity, MOUNJARO is used for weight management, including weight loss and weight maintenance.

2. What should I know before I use MOUNJARO?

Warnings

Do not use MOUNJARO if:

- you are allergic to tirzepatide, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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.

Check with your doctor if you:

- have any other medical conditions such as:
 - gastrointestinal disease, including severe gastroparesis (also called delayed gastric emptying), a condition affecting your digestive system. Your doctor may need to monitor your condition more closely and in some cases your doctor may need to change your dose or stop MOUNJARO if symptoms are severe.
 - malnutrition (your body does not get enough of the right nutrients to meet your body's needs).

- inflammation of the pancreas (pancreatitis) - an inflamed pancreas causing severe stomach and back pain which does not go away. MOUNJARO may cause inflammation of the pancreas.
- problems with your eyes (diabetic retinopathy). Your doctor may need to monitor your condition more closely while you are using MOUNJARO.
- thoughts of suicide or death.
- congestive heart failure.
- kidney impairment (kidneys are not working as well as they should).
- liver impairment (liver does not work as well as it should).
- are taking other medicines to treat type 2 diabetes (such as a sulfonylurea or insulin) as this may cause your blood sugar to be too low (hypoglycaemia). Your doctor may tell you to test your blood sugar to decide if any of the medicine/s or doses need to be changed.
- take any medicines for any other condition.
- have had an allergic reaction to any medicine which you have used previously to treat type 2 diabetes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Do not use MOUNJARO if you are pregnant as the effects of this medicine during pregnancy have not been studied.

If you could become pregnant while using MOUNJARO, it is recommended to use contraception.

It is unknown if MOUNJARO passes into breast milk. Talk to your doctor if you are breastfeeding or intend to breastfeed.

Dehydration

- When starting treatment with MOUNJARO, you may experience dehydration due to vomiting or diarrhoea.
- Dehydration can lead to kidney problems. **It is important to avoid dehydration by drinking plenty of fluids.**
- Symptoms of dehydration include dry mouth, decreased frequency of urination, dark urine, headache, muscle weakness, or dizziness. Check with your doctor if you have any questions or concerns.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with MOUNJARO and affect how it works.

When MOUNJARO is used with a medicine that contains sulfonylurea or insulin, hypoglycaemia can occur. The dose of your sulfonylurea or insulin may need to be reduced.

Some medicines may be affected by MOUNJARO and affect how they work.

MOUNJARO delays stomach (gastric) emptying. If you take any medicines via mouth (orally), such as slow-release medicines, medicines with quick absorption from the stomach, medicines that have a narrow therapeutic index (e.g., warfarin, digoxin), or an oral contraceptive ('the pill'), MOUNJARO may affect how well these medicines work. Check with your doctor or pharmacist if you are not sure.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MOUNJARO.

4. How do I use MOUNJARO?

How much to use

- When you first start using MOUNJARO, the starting dose is 2.5 mg once a week for 4 weeks. After 4 weeks your doctor will increase your dose to 5 mg once a week.
- Your doctor may increase your dose by 2.5 mg every 4 weeks to achieve a dose of 7.5 mg, 10 mg, 12.5 mg or 15 mg once a week if needed. The maximum dose is 15 mg once weekly.

- Follow the instructions provided and use MOUNJARO until your doctor tells you to stop. **Do not change your dose unless your doctor has told you to do so.** If you stop using it, your blood sugar levels may increase.

When to use MOUNJARO

- MOUNJARO should be used once a week, **on the same day each week** if you can.
- You can inject MOUNJARO at any time of the day, with or without meals.
- To help you remember, you may wish to write the day of the week when you take your first dose of MOUNJARO on a calendar.
- If necessary, you can change the day of your usual weekly injection of MOUNJARO as long as it has been at least 3 days since your last injection of MOUNJARO. Speak to your doctor, pharmacist or nurse if you are unsure.

How to use MOUNJARO

Follow all directions given to you by your doctor, pharmacist or nurse carefully. They may differ from the information contained in this leaflet.

How to inject MOUNJARO will be explained to you by a healthcare professional. After being trained by your healthcare professional, you can inject MOUNJARO yourself at home.

MOUNJARO must not be injected into a vein or muscle. MOUNJARO is intended for subcutaneous (under the skin) injection.

If you do not understand these instructions, ask your doctor, pharmacist or nurse for help.

When injecting, it is important to change the injection site to different areas of the body, to help reduce potential pain and irritation.

Areas with a good amount of fat below the skin (upper thigh, upper arm or stomach) are the most suitable areas to inject.

Prepare:

- **Inspect the vial carefully before using.** MOUNJARO should be clear and colourless to slightly yellow.
- **Check the name and coloured label** to make sure it is the correct medicine 'MOUNJARO' and it is the correct strength prescribed for you.
- Place all the items you will need on a clean surface where you will not be disturbed. These should include:
 - syringe with needle (as recommended by your healthcare provider).
 - A sharps container
- Wash your hands.
- Pull off the protective cap from the vial, but do not remove the rubber stopper.
- Firmly attach the needle to the top of the syringe. You can omit this step if the needle and syringe are already attached and in one piece.
- Remove the needle shield/cap.

Draw Up

- Push the needle through the centre of the rubber stopper of the vial.
- Leave the needle in the rubber stopper and turn the vial upside down.
- Slowly pull the plunger down until the plunger tip is past the 0.5 mL line.
- 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 the plunger tip reaches the 0.5 mL line.
- Pull the syringe out of the rubber stopper of the vial.

Inject

- You can use MOUNJARO under the skin (subcutaneous) of your stomach (abdomen) or upper leg (thigh) as you have been instructed. If MOUNJARO is given by someone else, they may inject in the back of your upper arm.
- If you want to do so, you can inject the same area of your body each week. But be sure to choose a different injection site within that area.
- If using a needle that is 8 mm or longer, pinch up a fold of skin and insert the needle into your skin at a 45 degree angle. For needles less than 8 mm, you can insert the needle into your skin at 90 degree angle, there is no need to pinch up the skin.
- Push down on the plunger to inject your dose.
- The plunger tip should be at the bottom of the syringe and the needle should stay in your skin for at least 5

seconds to make sure you have injected all of your medicine.

- Pull the needle out of your skin and place the needle directly into your sharps container. **Do not share or reuse your needle or syringe.**
- Dispose of the used vial (including any residue) in your sharps container.

If you forget to use MOUNJARO

MOUNJARO should be used regularly each week on the same day each week.

If you miss or forget your dose, it should be administered as soon as possible.

If there are fewer than 3 days until your next dose, then skip the missed dose. Inject the next MOUNJARO dose as usual on your regular day.

Do not take a double dose to make up for a forgotten dose.

If you use too much MOUNJARO

If you think that you have used too much MOUNJARO, seek urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MOUNJARO?

Things you should do

Remind any doctor, surgeon, anaesthetist, pharmacist or nurse you visit that you are using MOUNJARO.

Tell your doctor, pharmacist, or nurse if you are planning to travel overseas. You may not be able to get MOUNJARO in the country you are visiting, and you may need to carry a letter explaining why you are taking injecting devices with you. Your doctor, pharmacist or nurse can provide you with some helpful information.

If you have diabetes:

- Make sure all your family, relatives, friends, workmates, or carers know that you have diabetes and can recognise the symptoms of hypoglycaemia (low blood sugar).
- Let your doctor know if you start taking/using another medicine to treat type 2 diabetes. This could affect your blood sugar levels. Your doctor may want you to monitor your blood sugar levels more often.
- Always carry something to show you have diabetes.
- Always carry glucose or sugary foods with you.

- Let your doctor know if you plan to have any surgery or need general anaesthesia for any reason.

Call your doctor straight away if you:

- Experience severe low blood sugar, called hypoglycaemia, and this worries you.

Things you should not do

- Do not stop using this medicine suddenly and without consulting your Doctor/Healthcare provider.
- Do not use this medicine if you think it has been frozen or exposed to excessive heat, or if it is cloudy or contains particles. Appropriately discard and use a new vial for your injection.
- Do not use this medicine if the packaging is torn or shows signs of tampering.
- Do not give your MOUNJARO to anyone else, even if they have the same condition as you. Your doctor has prescribed MOUNJARO only for you.

Hypoglycaemia (low blood sugar) in patients with diabetes

It is important you know and can recognise the symptoms of hypoglycaemia.

Symptoms of mild to moderate hypoglycaemia can include:

- sweating
- hunger, headache

- tremor, unsteady movement
- light-headedness
- drowsiness, dizziness
- depressive mood, anxiety
- irritability, personality change
- abnormal behaviour
- inability to concentrate
- sleep disturbance
- blurred vision
- increased heart rate or irregular heartbeat
- tingling in the hands/feet/lips or tongue
- slurred speech

Tell your doctor, pharmacist or nurse if you have trouble recognising the symptoms of hypoglycaemia.

Recognising these mild to moderate hypoglycaemic symptoms early may allow you to take the necessary steps to avoid more serious hypoglycaemia.

Symptoms of severe hypoglycaemia can include:

- disorientation
- seizures
- unconsciousness

If you experience symptoms of hypoglycaemia, eat some sugary food or drink, such as jellybeans, orange juice or glucose tablets.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MOUNJARO affects you.

Hypoglycaemia (low blood sugar) may affect your ability to concentrate. Avoid driving or using machines if you get any signs of hypoglycaemia.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypoglycaemia (low blood sugar) or make it worse.

Looking after your medicine

- **Store MOUNJARO in a refrigerator (2°C - 8°C).**
- When refrigeration is not possible, you can keep your vial at room temperature (below 30°C) for up to a total of 21 days.
- **Do not allow the vial to freeze. DO NOT use if it has been frozen.**
- Keep MOUNJARO in the original package in order to protect from light.
- Never use MOUNJARO after the expiry date (month, year) stamped or printed on the carton, or on the label.

Keep it where young children cannot reach it.

When to discard your medicine

- If your doctor tells you to stop taking MOUNJARO, or
- If the expiry date on the carton or vial has passed.

Empty vials and used syringes and needles, should be disposed of in a yellow plastic sharps container or similar puncture proof container composed of hard plastic or glass. Ask your doctor, pharmacist, or nurse for further information.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor, pharmacist, or nurse if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Stomach related:</p> <ul style="list-style-type: none">• feeling sick (nausea)• diarrhoea (also refer to Serious Side Effects)• vomiting - this usually goes away over time (also refer to Serious Side Effects)• abdominal (stomach) pain (also refer to Serious Side Effects)• heartburn (typically a burning sensation that begins just below the breastbone and moves up towards the throat)• indigestion (dyspepsia) - discomfort in the upper stomach• swelling or bloating of the stomach which may be painful (abdominal distension)• constipation• burping or belching	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Less serious side effects	What to do
<ul style="list-style-type: none"> ● farting (flatulence) ● bloating and/or difficulty passing wind (farting) ● feeling less hungry (decreased appetite) <p>General disorders and injection site related:</p> <ul style="list-style-type: none"> ● general feeling of tiredness ● injection site reaction such as: redness, swelling or itching at the injection site. <p>Hypoglycaemia (low blood sugar):</p> <p>When MOUNJARO is used to treat diabetes together with:</p> <ul style="list-style-type: none"> ● a sulfonylurea (such as gliclazide, glibenclamide, glipizide) or insulin, ● metformin and an SGLT-2i (such as metformin and dapagliflozin, or metformin and empagliflozin, or 	

Less serious side effects	What to do
<p>metformin and ertugliflozin)</p> <p>Refer to Section 5 for signs and symptoms of hypoglycaemia.</p> <p>Other effects:</p> <ul style="list-style-type: none"> ● dizziness ● dehydration. <p>When initiating treatment with MOUNJARO, you may in some cases experience dehydration as a result of vomiting, nausea or diarrhoea. It is important to avoid dehydration by drinking plenty of fluids.</p> <ul style="list-style-type: none"> ● hair loss ● low blood pressure (hypotension) ● changes to how foods or drinks taste. ● changes to sensation or unusual feelings of the skin 	

Serious side effects

Serious side effects	What to do
<p>Acute pancreatitis:</p> <p>Symptoms of Inflamed pancreas (acute pancreatitis) may include:</p> <ul style="list-style-type: none">• severe pain in the stomach and back which does not go away; and• vomiting and/or diarrhoea <p>Allergic reactions:</p> <p>Symptoms of an allergic reaction may include:</p> <ul style="list-style-type: none">• rashes• itching and rapid swelling of the tissues of the neck, face, mouth and/or throat• hives (urticaria)• problems breathing or swallowing <p>Gallbladder complaints:</p> <ul style="list-style-type: none">• Gallstones or an inflamed gallbladder (symptoms may include	<p>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<p>sudden, severe pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), clay-coloured stools)</p>	
<p>Slowing down or blockage of intestinal function:</p> <p>Causing symptoms that may include:</p> <ul style="list-style-type: none"> ● severe pain in the stomach/abdomen ● bloating and/or difficulty passing wind (farting) ● feeling sick (nausea), vomiting and/or diarrhoea ● constipation/bowel urges with no resulting movement 	<p>Tell your doctor as soon as possible.</p>

Tell your doctor, pharmacist or nurse if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What MOUNJARO contains

Active ingredient (main ingredient)	tirzepatide
Other ingredients (inactive ingredients)	dibasic sodium phosphate heptahydrate sodium chloride hydrochloric acid sodium hydroxide water for injections

Potential allergens	none
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Do not take this medicine if you are allergic to any of these ingredients.

MOUNJARO vials are for single-use and do not contain any preservative. Discard after use.

What MOUNJARO looks like

MOUNJARO is a clear, colourless to slightly yellow solution available as a single-use vial.

MOUNJARO vials are available in the following strengths:

- 2.5 mg/0.5 mL (AUST R 407055)
- 5.0 mg/0.5 mL (AUST R 407050)
- 7.5 mg/0.5 mL (AUST R 407051)
- 10 mg/0.5 mL (AUST R 407053)
- 12.5 mg/0.5 mL (AUST R 407052)
- 15 mg/0.5 mL (AUST R 407054)

Who distributes MOUNJARO

Australia:

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street,

Sydney, NSW 2000

Further Information

If you have any questions about MOUNJARO, contact Lilly at 1800 454 559 or your healthcare professional for assistance.

To check for CMI updates and obtain the latest version, visit www.ebs.tga.gov.au

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