MOUNJARO® KwikPen® pre-filled pen

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 KwikPen?

MOUNJARO KwikPen contains the active ingredient tirzepatide. In adults, adolescents and children aged 10 years and above weighing 50 kg or more, with type 2 diabetes, MOUNJARO KwikPen is used to improve blood sugar control. In adults who are overweight or have obesity, MOUNJARO KwikPen is used for weight management. In adults who have obesity, MOUNJARO KwikPen is also used to treat moderate to severe obstructive sleep apnoea. For more information, see Section 1. Why am I using MOUNJARO KwikPen? in the full CMI.

2. What should I know before I use MOUNJARO KwikPen?

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 KwikPen? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MOUNJARO KwikPen 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 KwikPen?

MOUNJARO KwikPen is supplied as a multiple-dose (4 doses), pre-filled Pen that is used once a week, **on the same day each week** if you can. When you first start using MOUNJARO KwikPen, 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.

More instructions can be found in Section 4. How do I use MOUNJARO KwikPen? in the full CMI.

5. What should I know while using MOUNJARO KwikPen?

Things you should do	• Remind any doctor, surgeon, anaesthetist, pharmacist, or nurse you visit that you are using MOUNJARO KwikPen. • 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	• 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	• Be careful before you drive or use machines or tools until you know how MOUNJARO affects you. • Hypoglycaemia (low blood sugar) may affect your ability to concentrate.
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 KwikPen in a refrigerator (2°C - 8°C). Do not freeze. • Keep MOUNJARO KwikPen 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 KwikPen? in the full CMI.

6. Are there any side effects?

The most common side effects are nausea, diarrhoea, vomiting and constipation. 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, loss of vision 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® KwikPen® pre-filled pen (muhn-JAHR-oh)

Active ingredient: *tirzepatide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using MOUNJARO KwikPen. **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 KwikPen.**

Where to find information in this leaflet:

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

1. Why am I using MOUNJARO KwikPen?

MOUNJARO KwikPen contains the active ingredient tirzepatide. MOUNJARO KwikPen is a type of medicine called 'GIP and GLP-1 receptor agonists'.

- In adults, adolescents and children aged 10 years and above weighing 50 kg or more, 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.
- In adults with obesity, this medicine is also used to treat moderate to severe obstructive sleep apnoea (OSA).

Type 2 diabetes mellitus (T2DM)

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

In adults, adolescents and children aged 10 years and above weighing 50 kg or more, with type 2 diabetes, MOUNJARO KwikPen is used to improve blood sugar control.

MOUNJARO KwikPen 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 KwikPen is used for weight management, including weight loss and weight maintenance.

Obstructive Sleep Apnoea (OSA).

In adults with obesity, MOUNJARO KwikPen is used to treat moderate to severe obstructive sleep apnoea (OSA). OSA is a disease causing frequent brief interruptions of breathing during sleep.

MOUNJARO KwikPen may be used together with or without positive airway pressure (PAP) therapy. Check with your doctor if you are unsure or need further information.

2. What should I know before I use MOUNJARO KwikPen?

Warnings

Do not use MOUNJARO KwikPen 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 under 10 years of age for the treatment of type 2 diabetes
- children and adolescents under 18 years of age who weigh less than 50 kg for the treatment of type 2 diabetes
- children and adolescents under 18 years of age for weight loss or obstructive sleep apnoea.

This medicine has not been studied in these age groups, weight ranges or conditions.

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 KwikPen 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 KwikPen 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 KwikPen.
  - thoughts of suicide or death.
  - congestive heart failure.

- 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.
- you have kidney or liver disease/impairment (kidneys or liver are not working as well as they should). Each MOUNJARO KwikPen contains 5.4 mg benzyl alcohol in each 0.6 mL dose. Benzyl alcohol may cause allergic reactions. Large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

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

If you intend to become pregnant, stop using MOUNJARO KwikPen at least one month before a planned pregnancy.

If there is a chance you could become pregnant while using MOUNJARO KwikPen, it is recommended to use contraception (birth control).

MOUNJARO KwikPen may affect how well birth control taken by mouth ('the pill') works. If you already take the pill:

- Switch to a different type of birth control medicine, or
- Add a barrier method of birth control (e.g., condoms). Use this barrier method for 4 weeks when beginning treatment with MOUNJARO KwikPen and for 4 weeks after each time your dose is increased.

Talk to your doctor before using MOUNJARO KwikPen if you are breastfeeding or intend to breastfeed. A risk to newborns/infants cannot be excluded. You and your doctor should decide if you should stop breastfeeding or delay using MOUNJARO KwikPen.

Dehydration

- When starting treatment with MOUNJARO KwikPen, 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 KwikPen and affect how it works.

When MOUNJARO KwikPen 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 KwikPen and affect how they work.

MOUNJARO KwikPen 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), medicines that need to reach a certain level in the body before they are effective, or an oral birth control ('the pill'), MOUNJARO KwikPen 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 KwikPen.

4. How do I use MOUNJARO KwikPen?

How much to use

Adults

- When you first start using MOUNJARO KwikPen, 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.

Adolescents and children aged 10 years and above weighing 50 kg or more being treated for type 2 diabetes

- 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 10 mg once a week if needed.
- The maximum dose is 10 mg once weekly.

Follow the instructions provided and use MOUNJARO KwikPen 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 KwikPen

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

How to use MOUNJARO KwikPen

Read the Instructions for Use leaflet contained in the carton carefully before using MOUNJARO KwikPen.

Follow all directions given to you by your doctor, nurse, or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand these instructions, ask your doctor, nurse, or pharmacist for help.

If you are below 18 years of age, a caregiver may give you your MOUNJARO KwikPen injection or you may self-inject if your healthcare professional determines that it is appropriate.

- **Inspect the pre-filled Pen carefully before using.** MOUNJARO KwikPen should be clear and colourless to slightly yellow.
- **Check the name and coloured label** of your Pen to make sure it is the correct medicine 'MOUNJARO KwikPen' and is the correct strength prescribed for you.
- To avoid underdosing (injecting too little of the medicine), ensure the dose knob on the MOUNJARO KwikPen is turned until it stops at the ‘1’ icon (see step-by-step instructions in the Instructions for Use leaflet in the carton).
- Inject MOUNJARO KwikPen under the skin (subcutaneous) of your stomach (abdomen) or upper leg (thigh). MOUNJARO KwikPen must not be injected into a vein or muscle.

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

MOUNJARO KwikPen leftover medicine

- The MOUNJARO **KwikPen contains 4 fixed doses.**
- There will be some medicine still left in the KwikPen after these 4 doses. This is normal. Throw away (discard) the KwikPen after using the 4 doses.
- The Pen will prevent you from dialing a full 0.6 mL dose after you have given yourself 4 weekly doses.
- **Do not** inject the leftover medicine.

If you forget to use MOUNJARO KwikPen

MOUNJARO KwikPen 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 KwikPen 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 KwikPen

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 in New Zealand**), 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 KwikPen?

Things you should do

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

Tell your doctor, pharmacist, or nurse if you are planning to travel overseas. You may not be able to get MOUNJARO KwikPen 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.

- Ask your doctor or pharmacist for advice if you have a liver or kidney disease. Each 0.6 mL dose in the MOUNJARO KwikPen contains 5.4 mg benzyl alcohol. Benzyl alcohol may cause allergic reactions. Large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

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 Pen for your injection.
- Do not use this medicine if the packaging is torn or shows signs of tampering.
- Do not give your MOUNJARO KwikPen to anyone else, even if they have the same condition as you. Your doctor has prescribed MOUNJARO KwikPen 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 KwikPen 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 KwikPen in a refrigerator (2°C - 8°C).
- When refrigeration is not possible, you can keep your Pen at room temperature (below 30°C) for up to a total of 30 days.
- **Do not allow the KwikPen to freeze. DO NOT use if it has been frozen.**

- MOUNJARO KwikPen contains glass parts. Handle it carefully. If you drop your MOUNJARO KwikPen on a hard surface, DO NOT use it. Appropriately discard it and use a new Pen for your injection.
- Keep MOUNJARO KwikPen in the original package in order to protect from light.
- Never use MOUNJARO KwikPen after the expiry date (month, year) stamped or printed on the carton, or on the Pen label.

Follow the Instructions for Use leaflet in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

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

Discard KwikPens after the final dose (fourth injection) has been administered. There will be a small amount of leftover medicine remaining in the KwikPen after the final dose (fourth injection), this is normal.

Dispose of KwikPens 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
Stomach related: • 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)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• 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 • farting (flatulence) • bloating and/or difficulty passing wind (farting) • feeling less hungry (decreased appetite) **General disorders and injection site related:** • general feeling of tiredness • injection site reaction such as: redness, swelling or itching at the injection site.	

Less serious side effects	What to do
Hypoglycaemia (low blood sugar): When MOUNJARO KwikPen is used to treat diabetes together with: • a sulfonylurea (such as gliclazide, glibenclamide, glipizide) or insulin, • metformin **and** an SGLT-2i (such as metformin and dapagliflozin, or metformin and empagliflozin, or metformin and ertugliflozin) Refer to Section 5 for signs and symptoms of hypoglycaemia. **Other effects:** • dizziness • dehydration When initiating treatment with MOUNJARO KwikPen, you may in some cases experience dehydration as a result	

Less serious side effects	What to do
of vomiting, nausea or diarrhoea. It is important to avoid dehydration by drinking plenty of fluids. • 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
Acute pancreatitis: Symptoms of Inflamed pancreas (acute pancreatitis) may include: • severe pain in the stomach and back which does not go away; **and** • vomiting and/or diarrhoea **Allergic reactions:**	**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.**

Serious side effects	What to do
Symptoms of an allergic reaction may include: • rashes • itching and rapid swelling of the tissues of the neck, face, mouth and/or throat • hives (urticaria) • problems breathing or swallowing **Gallbladder complaints:** • Gallstones or an inflamed gallbladder (symptoms may include sudden, severe pain in your upper stomach (abdomen), fever, yellowing of skin or eyes (jaundice), clay-coloured stools) **Vision related** • changes to, or loss of vision	
Slowing down or blockage of intestinal function:	**Tell your doctor as soon as possible.**

Serious side effects	What to do
Causing symptoms that may include: • 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	

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:

- Australia: Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems
- New Zealand: online at https://pophealth.my.site.com/carmreportnz/s/

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 KwikPen contains

Active ingredient **(main ingredient)**	tirzepatide
Other ingredients **(inactive ingredients)**	dibasic sodium phosphate heptahydrate benzyl alcohol glycerol phenol sodium chloride hydrochloric acid sodium hydroxide water for injections
Potential allergens	none

Do not take this medicine if you are allergic to any of these ingredients.

What MOUNJARO KwikPen looks like

MOUNJARO KwikPen is a clear, colourless to slightly yellow solution available as a multiple-dose (4 doses), pre-filled Pen.

No needles are included in the pack.

MOUNJARO KwikPen is available in the following strengths:

Quantity per dose **(dose volume = 0.6 mL)**	**Quantity expressed per 1 mL**	**AUST R number**	**TT50 (NZ)**
2.5 mg/dose	4.17 mg/mL	439430	TT50-11479
5 mg/dose	8.33 mg/mL	439690	TT50-11479a
7.5 mg/dose	12.5 mg/mL	439691	TT50-11479b
10 mg/dose	16.67 mg/mL	439692	TT50-11479c
12.5 mg/dose	20.83 mg/mL	439693	TT50-11479d
15 mg/dose	25 mg/mL	439694	TT50-11479e

Who distributes MOUNJARO KwikPen

Australia:

Eli Lilly Australia Pty Ltd

Level 9, 60 Margaret Street

Sydney NSW 2000

New Zealand:

Eli Lilly and Company (NZ) Limited

PO Box 109 197

Newmarket, Auckland 1149

Further Information

If you have any questions about MOUNJARO KwikPen, contact Lilly at 1800 454 559 (Australia), or 0800 500 056 (New Zealand) or your healthcare professional for assistance.

To check for CMI updates and obtain the latest version, visit:

- Australia: www.ebs.tga.gov.au
- New Zealand: www.medsafe.govt.nz

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