Applicant:	Eli Lilly (S.A.) (Pty) Limited	**Date:** 09/12/2025
Proprietary Name(s):	MOUNJARO 2,5 mg, 5 mg , 7,5 mg, 10 mg, 12,5 mg, 15 mg & MOUNJARO 2,5 mg, 5 mg , 7,5 mg, 10 mg, 12,5 mg, 15 mg KWIKPEN	
Active ingredient:	Tirzepatide	
Dosage Form and Strength:	Solution for Injection; 2,5 mg; 5 mg; 7,5 mg; 10 mg; 12,5 mg; 15 mg	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

MOUNJARO 2,5 mg Solution for Injection

MOUNJARO 5 mg Solution for Injection

MOUNJARO 7,5 mg Solution for Injection

MOUNJARO 10 mg Solution for Injection

MOUNJARO 12,5 mg Solution for Injection

MOUNJARO 15 mg Solution for Injection

MOUNJARO 2,5 mg KwikPen Solution for Injection

MOUNJARO 5 mg KwikPen Solution for Injection

MOUNJARO 7,5 mg KwikPen Solution for Injection

MOUNJARO 10 mg KwikPen Solution for Injection

MOUNJARO 12,5 mg KwikPen Solution for Injection

MOUNJARO 15 mg KwikPen Solution for Injection

Tirzepatide

Read all of this leaflet carefully before you start using MOUNJARO

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider

- MOUNJARO has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 take 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

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/m^2). 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.

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

2. What you need to know before you take MOUNJARO

Do not use MOUNJARO if you:

- are allergic to tirzepatide or to any of the other ingredients of MOUNJARO (listed in section 6)

- or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using MOUNJARO if:

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- 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

MOUNJARO 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. (this includes complementary or traditional medicines)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MOUNJARO.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using MOUNJARO. MOUNJARO should not be used during pregnancy as the effects on an unborn child are not known. Therefore, it is recommended to use contraception while using MOUNJARO.

Breastfeeding

You should not breastfeed your infant when taking MOUNJARO. It is unknown whether tirzepatide passes into breast milk. A risk to newborns/infants cannot be ruled

out. If you are breastfeeding or are planning to breastfeed, talk to your doctor before using MOUNJARO.

Driving and using machines

It is unlikely that MOUNJARO 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 2, 'Warnings and precautions' for information on increased risk of low blood sugar. Talk to your doctor for further information.

MOUNJARO contains sodium

MOUNJARO contains less than 1 mmol sodium (23 mg) per dose, essentially 'sodium-free'.

MOUNJARO KwikPen contains benzyl alcohol

MOUNJARO KwikPen contains 5,4 mg benzyl alcohol in each 0,6 ml dose. Benzyl alcohol may cause allergic reactions.

Ask your doctor, pharmacist or nurse for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl

alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to use MOUNJARO

Do not share medicines prescribed for you with any other person.

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

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 or vial contains one dose of MOUNJARO either 2,5 mg, 5 mg, 7,5 mg, 10 mg, 12,5 mg, or 15 mg.

Each KwikPen contains 4 doses of MOUNJARO either 2,5 mg, 5 mg, 7,5 mg, 10 mg, 12,5 mg, or 15 mg.

Choosing when to give MOUNJARO

You can use your MOUNJARO 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

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

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”, included in the pack, 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').

If you take 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 MOUNJARO, ask your doctor, pharmacist or nurse.

4. Possible side effects

Not all side effects reported for MOUNJARO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MOUNJARO, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

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.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

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. They are most common when first starting MOUNJARO but decrease over time in most patients.

- Low blood sugar (hypoglycaemia) is very common when MOUNJARO 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 MOUNJARO (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 MOUNJARO 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
- Being sick (vomiting) – this usually goes away over time
- Indigestion (dyspepsia)
- Constipation
- 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.

Uncommon (may affect up to 1 in 100 people)

- Low blood sugar (hypoglycaemia) when MOUNJARO 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.
- Changed sense of taste

- Change in skin sensation
- A delay in the emptying of the stomach

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MOUNJARO.

Alternately, report suspected adverse events to the company at: ade_za@lilly.com

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 label and on the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C). Do not freeze. If the pen has been frozen, DO NOT USE.

Do not use MOUNJARO if you notice that the pen, vial, seal or stopper 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.

Pre-filled pen or Vial, single-dose:

Store in the original packaging to protect from light.

MOUNJARO can be stored unrefrigerated below 30 ºC for up to 21 cumulative days and then the pen or vial must be discarded.

Pre-filled pen (KwikPen), multi-dose:

MOUNJARO KwikPen can be stored unrefrigerated below 30 ºC for up to 30 days after first use and then the pen must be discarded.

6. Contents of the pack and other information

What MOUNJARO contains

The active substance is tirzepatide.

MOUNJARO 2,5 mg Solution for Injection – Each pre-filled pen or vial contains 2,5 mg of tirzepatide in 0,5 ml solution for injection.

MOUNJARO 5 mg Solution for Injection - Each pre-filled pen or vial contains 5 mg of tirzepatide in 0,5 ml solution for injection.

MOUNJARO 7,5 mg Solution for Injection - Each pre-filled pen or vial contains 7,5 mg of tirzepatide in 0,5 ml solution for injection.

MOUNJARO 10 mg Solution for Injection - Each pre-filled pen or vial contains 10 mg of tirzepatide in 0,5 ml solution for injection.

MOUNJARO 12,5 mg Solution for Injection - Each pre-filled pen or vial contains 12,5 mg of tirzepatide in 0,5 ml solution for injection.

MOUNJARO 15 mg Solution for Injection - Each pre-filled pen or vial contains 15 mg of tirzepatide in 0,5 ml solution for injection.

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.

MOUNJARO 2,5 mg KwikPen Solution for Injection – Each dose contains 2,5 mg of tirzepatide in 0,6 ml solution. Each multi-dose pre-filled pen contains 10 mg of tirzepatide in 2,4 ml (4,17 mg/ml). Each pen delivers 4 doses of 2,5 mg.

MOUNJARO 5 mg KwikPen Solution for Injection - Each dose contains 5 mg of tirzepatide in 0,6 ml solution. Each multi-dose pre-filled pen contains 20 mg of tirzepatide in 2,4 ml (8,33 mg/ml). Each pen delivers 4 doses of 5 mg.

MOUNJARO 7,5 mg KwikPen Solution for Injection - Each dose contains 7,5 mg of tirzepatide in 0,6 ml solution. Each multi-dose pre-filled pen contains 30 mg of tirzepatide in 2,4 ml (12,5 mg/ml). Each pen delivers 4 doses of 7,5 mg.

MOUNJARO 10 mg KwikPen Solution for Injection - Each dose contains 10 mg of tirzepatide in 0,6 ml solution. Each multi-dose pre-filled pen contains 40 mg of tirzepatide in 2,4 ml (16,7 mg/ml). Each pen delivers 4 doses of 10 mg.

MOUNJARO 12,5 mg KwikPen Solution for Injection - Each dose contains 12,5 mg of tirzepatide in 0,6 ml solution. Each multi-dose pre-filled pen contains 50 mg of tirzepatide in 2,4 ml (20,8 mg/ml). Each pen delivers 4 doses of 12,5 mg.

MOUNJARO 15 mg KwikPen Solution for Injection - Each dose contains 15 mg of tirzepatide in 0,6 ml solution. Each multi-dose pre-filled pen contains 60 mg of tirzepatide in 2,4 ml (25 mg/ml). Each pen delivers 4 doses of 15 mg.

The other ingredients are sodium phosphate dibasic heptahydrate, benzyl alcohol (see section 2 under 'MOUNJARO KwikPen contains benzyl alcohol' for further information), glycerol, phenol, 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

Pre-filled pen and vial, single-dose:

MOUNJARO is a clear to opalescent, colourless to slightly yellow or brown solution, essentially free of particles, for injection in a pre-filled pen or vial.

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 or vial contains 0,5 ml solution.

The pre-filled pen or vial is for single use only.

Pre-filled pen (KwikPen), multi-dose:

MOUNJARO KwikPen is a clear to opalescent, colourless to slightly yellow or brown solution, essentially free of particles, for injection in a pre-filled pen (KwikPen).

Each KwikPen contains 2,4 ml solution for injection (4 doses of 0,6 ml), and excess for priming. Needles are not included.

Pack sizes:

Pre-filled pen, single dose: 2 pre-filled pens, 4 pre-filled pens or multipacks of 12 (3 packs of 4) pre-filled pens.

Vial, single dose: 1 vial, 4 vials, 12 vials, multipack containing 4 (4 packs of 1) vials or multipack containing 12 (12 packs of 1) vials.

Pre-filled pen (KwikPen), multi-dose: 1 and 3 pre-filled KwikPens

Not all pack sizes may be available.

Holder of the Certificate of Registration

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Registration number

MOUNJARO 2,5 mg Solution for Injection - 57/21.13/0821

MOUNJARO 5 mg Solution for Injection - 57/21.13/0822

Applicant: Eli Lilly (S.A.) (Pty) Limited **Date:** 09/12/2025
Proprietary Name(s): MOUNJARO 2,5 mg, 5 mg , 7,5 mg, 10 mg, 12,5 mg, 15 mg &
MOUNJARO 2,5 mg, 5 mg , 7,5 mg, 10 mg, 12,5 mg, 15 mg KWIKPEN
Active ingredient: Tirzepatide
Dosage Form and Strength: Solution for Injection; 2,5 mg; 5 mg; 7,5 mg; 10 mg; 12,5 mg; 15 mg

MOUNJARO 7,5 mg Solution for Injection - 57/21.13/0823

MOUNJARO 10 mg Solution for Injection - 57/21.13/0824

MOUNJARO 12,5 mg Solution for Injection - 57/21.13/0825

MOUNJARO 15 mg Solution for Injection - 57/21.13/0826

MOUNJARO 2,5 mg KwikPen Solution for Injection - 60/21.13/0282

MOUNJARO 5 mg KwikPen Solution for Injection - 60/21.13/0283

MOUNJARO 7,5 mg KwikPen Solution for Injection - 60/21.13/0284

MOUNJARO 10 mg KwikPen Solution for Injection - 60/21.13/0285

MOUNJARO 12,5 mg KwikPen Solution for Injection - 60/21.13/0286

MOUNJARO 15 mg KwikPen Solution for Injection - 60/21.13/0287