

MOUNJARO KWIKPEN SOLUTION FOR INJECTION IN PRE-FILLED PEN

Tirzepatide (2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg)

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What Mounjaro KwikPen is used for

Mounjaro is an injectable prescription medicine for adults that contains an active substance called tirzepatide and is used to treat adults with type 2 diabetes mellitus.

Mounjaro is also used to treat adults with obesity or overweight (with BMI of at least 27 kg/m²).

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, nurse or pharmacist.

How Mounjaro KwikPen works

Mounjaro controls blood sugar levels along with diet and exercise. Mounjaro reduces the level of sugar in the body only when the levels of sugar are high.

Mounjaro influences appetite regulation, which may help you eat less food and reduce your body weight.

Before you use Mounjaro KwikPen

- When you must not use it

- If you are allergic to tirzepatide or any of the other ingredients of this medicine (listed under *Ingredients*).

- Before you start to use it

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.

Mounjaro KwikPen contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

Mounjaro KwikPen contains benzyl alcohol

This medicine contains 5.4 mg benzyl alcohol in each 0.6 ml dose. Benzyl alcohol may cause allergic reactions.

Ask your doctor, nurse or pharmacist 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").

- Taking other medicines

Tell your doctor, nurse or pharmacist if you are using, have recently used or might use any other medicines.

How to use Mounjaro KwikPen

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.

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 KwikPen.

- How much to use

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.

- 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.

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- When to use it

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 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 long to use it

Continue taking Mounjaro KwikPen for as long as your doctor recommends.

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 *Before you start to use it*).

- If you forget to use it

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 use too much (overdose)

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.

While you are using Mounjaro KwikPen

- Things you must do

Tell your doctor, nurse or pharmacist if you are using, have recently used or might use any other medicines.

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

- Things you must not do

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.

- Things to be careful of

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.

Pregnancy and breast-feeding

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.

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 *Side Effects*). See section 'Before you start to use it' under *Before you use Mounjaro KwikPen* for information on increased risk of low blood sugar. Talk to your doctor for further information.

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 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.

- Other side effects

Very common (may affect more than 1 in 10 people)

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

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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 *Before you use Mounjaro KwikPen*). 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.

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 may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Mounjaro KwikPen

- Storage

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.

Mounjaro KwikPen can be stored unrefrigerated below 30 °C for up to 30 days after first use 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.

- Disposal

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.

Product Description

- What it looks like

Mounjaro is a clear, colourless to slightly yellow, solution 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 size of 1 KwikPen.

- Ingredients

- Active ingredient
The active substance is tirzepatide.

- *Mounjaro 2.5 mg KwikPen*: 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*: 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*: 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*: 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*: 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

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delivers 4 doses of 12.5 mg.

- *Mounjaro 15 mg KwikPen*: 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.

Date of Revision

29/04/2025

Serial Number

NPRA (R1) 25/012

- **Inactive ingredients**

The other ingredients are disodium hydrogen phosphate heptahydrate (E339), benzyl alcohol (E1519) (see section 'Mounjaro KwikPen contains benzyl alcohol' under *Before you use Mounjaro KwikPen* for further information), glycerol, phenol, sodium chloride, sodium hydroxide (see section 'Mounjaro KwikPen contains sodium' under *Before you use Mounjaro KwikPen* for further information); concentrated hydrochloric acid and water for injections.

- **MAL number**

Mounjaro 2.5 mg KwikPen solution for injection in pre-filled pen –MALXXXXXXXX

Mounjaro 5 mg KwikPen solution for injection in pre-filled pen –MALXXXXXXXX

Mounjaro 7.5 mg KwikPen solution for injection in pre-filled pen –MALXXXXXXXX

Mounjaro 10 mg KwikPen solution for injection in pre-filled pen –MALXXXXXXXX

Mounjaro 12.5 mg KwikPen solution for injection in pre-filled pen –MALXXXXXXXX

Mounjaro 15 mg KwikPen solution for injection in pre-filled pen –MALXXXXXXXX

Manufacturer

Eli Lilly Italia S.P.A.
V.Gramsci 731-733
50019, Sesto Fiorentino (FI)

Product Registration Holder

Zuellig Pharma Sdn Bhd
No. 15 Persiaran Pasak Bumi,
Seksyen U8, Perindustrian Bukit
Jelutong, 40150 Shah Alam,
Selangor, Malaysia
