

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

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

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

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

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

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

(tirzepatide)

UK511010P99-A.1.2

1. What Mounjaro KwikPen is and what it is used for

▼ 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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Mounjaro 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12 mg, 15 mg KwikPen solution for injection in pre-filled pen but will be referred to as Mounjaro KwikPen in this leaflet.

What is in this leaflet

- What Mounjaro KwikPen is and what it is used for
- What you need to know before you use Mounjaro KwikPen
- How to use Mounjaro KwikPen
- Possible side effects
- How to store Mounjaro KwikPen
- Contents of the pack and other information

1. What Mounjaro KwikPen is and what it is used for

What Mounjaro is

Mounjaro is a medicine that contains an active substance called tirzepatide. Mounjaro is used to treat adults with type 2 diabetes mellitus by reducing the level of sugar in the body only when the levels of sugar are high. Mounjaro is also used for weight loss and weight maintenance in adults. Mounjaro primarily works by regulating your appetite, giving you a sense of satiety ('fullness'), making you feel less hungry and experience less food cravings. This will help you eat less food and reduce your body weight.

What Mounjaro is used for

- 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.

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

Mounjaro is also used together with reduced-calorie diet and increased physical activity 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' (OSA) 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.

2. What you need to know before you use Mounjaro KwikPen

Do not use Mounjaro KwikPen

- 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, 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; see section 4).
- 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, pharmacist or nurse if you are using, have recently used or might use any other medicines.

Pregnancy

This medicine should not be used during pregnancy as the effects of this medicine on an unborn child are not known. 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. It is recommended to use contraception while using this medicine.

If you are a woman with obesity or overweight and are using oral contraceptives, you should consider also using a barrier method of contraception (e.g., a condom) or switching to a non-oral contraceptive method for 4 weeks after starting Mounjaro and for 4 weeks after each increase in dose.

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 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

Each multiple-dose pre-filled pen contains 5.4 mg Benzyl Alcohol [E1519] in each 0.6 ml dose. Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice 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 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.

Each KwikPen contains 4 doses of Mounjaro either 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg, or 15 mg.

A small amount of medicine may remain in the pen after all doses have been correctly given. Do not try to use any remaining medicine. After administration of the last dose, the pen must be properly discarded.

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.

Choosing when to give 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 "Instructions for Use" 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 KwikPen

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.

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.

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 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, pharmacist or nurse.

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. This is a serious, potentially life-threatening condition. You should see a doctor immediately if you experience such symptoms.

Stop using this medicine and seek urgent medical help if you experience:

- Severe, persistent pain in the stomach area (abdomen), with or without nausea and vomiting. This could be a sign of acute pancreatitis, which is serious and potentially life-threatening.

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)

- Low blood sugar (hypoglycaemia) when tirzepatide is used for the treatment of type 2 diabetes with medicines that contain a sulphonylurea and/or insulin. If you are using a sulphonylurea or insulin, 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.
- Feeling sick (nausea)*
- Diarrhoea*
- Being sick (vomiting) – this usually goes away over time**
- Stomach (abdominal) pain¹
- Constipation¹.

**These side effects are usually not severe. They are most common when first starting tirzepatide but decrease over time in most patients.*

¹*Constipation, abdominal pain, and vomiting are very common in patients treated for weight management, but common in patients treated for type 2 diabetes.*

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). 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.
- Allergic reaction (hypersensitivity) (e.g., rash, itching, and eczema)
- Dizziness observed in patients treated for weight management
- Low blood pressure observed in patients treated for weight management
- Feeling less hungry (decreased appetite) observed in patients treated for type 2 diabetes
- Indigestion (dyspepsia)
- Bloating of the stomach
- Burping (eructation)

- Gas (flatulence)
- Reflux or heartburn (also called gastroesophageal reflux disease - GORD) - a disease caused by stomach acid coming up into the tube from your stomach to your mouth
- Hair loss observed in patients treated for weight management
- Feeling tired (fatigue)
- Injection site reactions (e.g. itching or redness)
- Fast pulse¹
- Increased levels of pancreatic enzymes (such as lipase and amylase²) in blood
- Increased calcitonin levels in blood³
- Gallstones³

¹Fast pulse is a common side effect when used for type 2 diabetes and uncommon when used for weight management.

²Increased levels of amylase is uncommon in weight management.

³Increased calcitonin levels in blood and gallstones are common when used for weight management, but uncommon when used for type 2 diabetes.

Uncommon (may affect up to 1 in 100 people)

- Low blood sugar (hypoglycaemia) when tirzepatide is used with metformin for type 2 diabetes. 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.
- Weight loss observed in patients treated for type 2 diabetes
- Injection site pain
- Cholecystitis (infection of the gallbladder) observed in patients treated for weight management
- Changed sense of taste
- Change in skin sensation
- A delay in the emptying of the stomach.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Mounjaro KwikPen

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 not above 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.

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.

If the medicine becomes discolored or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.

6. Contents of the pack and other information

What Mounjaro KwikPen contains

- The active substance is tirzepatide.
- Mounjaro 2.5 mg KwikPen:* Each multiple-dose pre-filled pen contains 4 doses of 0.6 ml solution which can be administered. Each dose (0.6 ml) contains 2.5 mg of tirzepatide.
- Mounjaro 5 mg KwikPen:* Each multiple-dose pre-filled pen contains 4 doses of 0.6 ml solution which can be administered. Each dose (0.6 ml) contains 5 mg of tirzepatide.
- Mounjaro 7.5 mg KwikPen:* Each multiple-dose pre-filled pen contains 4 doses of 0.6 ml solution which can be administered. Each dose (0.6 ml) contains 7.5 mg of tirzepatide.
- Mounjaro 10 mg KwikPen:* Each multiple-dose pre-filled pen contains 4 doses of 0.6 ml solution which can be administered. Each dose (0.6 ml) contains 10 mg of tirzepatide.
- Mounjaro 12.5 mg KwikPen:* Each multiple-dose pre-filled pen contains 4 doses of 0.6 ml solution which can be administered. Each dose (0.6 ml) contains 12.5 mg of tirzepatide.
- Mounjaro 15 mg KwikPen:* Each multiple-dose pre-filled pen contains 4 doses of 0.6 ml solution which can be administered. Each dose (0.6 ml) contains 15 mg of tirzepatide.

The other ingredients are sodium phosphate dibasic heptahydrate, benzyl alcohol, 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

Mounjaro is a clear, colourless to slightly yellow, solution for injection in a pre-filled KwikPen. Each pre-filled KwikPen contains 4 doses of 0.6 ml which can be administered. Any excess solution in the pen after use should be discarded. The pre-filled KwikPen is for multiple-dose. Each pre-filled KwikPen contains 4 doses.

Pack size of 1 pre-filled KwikPen.

Manufacturer

Lilly S.A.
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28108 Alcobendas, Madrid
Spain

or

Eli Lilly Italia S.p.A.
Via Gramsci 731/733
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Procured from within the EU and repackaged for the PL Holder:

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GU14 7NA, United Kingdom

Mounjaro® 2.5 mg KwikPen® solution for injection in pre-filled pen PL 45763/1013
Mounjaro® 5 mg KwikPen® solution for injection in pre-filled pen PL 45763/1012
Mounjaro® 7.5 mg KwikPen® solution for injection in pre-filled pen PL 45763/1014
Mounjaro® 10 mg KwikPen® solution for injection in pre-filled pen PL 45763/1011
Mounjaro® 12.5 mg KwikPen® solution for injection in pre-filled pen PL 45763/1009
Mounjaro® 15 mg KwikPen® solution for injection in pre-filled pen PL 45763/1010

POM

This leaflet was last revised on 18/11/2025.

For any information about this medicine, please contact the local representative of the Product Licence Holder:
Abacus Medicine Ltd.
tel: +44(0)2036301244,
email: MedInfo@abacusmedicine.co.uk or
drugsafetyuk@abacusmedicine.co.uk

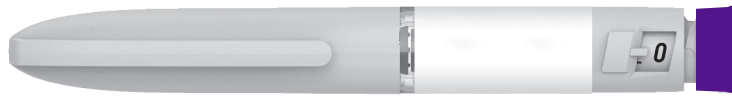
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Is this leaflet hard to see or read?
Call 02036301310 or write
to info@abacusmedicine.com
to obtain the leaflet in a format
suitable for you.**

Instructions for use

injection, for subcutaneous use
Multi-dose single-patient-use pre-filled pen
Each pen contains 4 fixed doses, one dose taken weekly.

Mounjaro® 2.5 mg KwikPen® solution for injection in pre-filled pen
Mounjaro® 5 mg KwikPen® solution for injection in pre-filled pen
Mounjaro® 7.5 mg KwikPen® solution for injection in pre-filled pen
Mounjaro® 10 mg KwikPen® solution for injection in pre-filled pen
Mounjaro® 12.5 mg KwikPen® solution for injection in pre-filled pen
Mounjaro® 15 mg KwikPen® solution for injection in pre-filled pen (tirzepatide)

This Instructions for Use contains information on how to inject Mounjaro KwikPen.

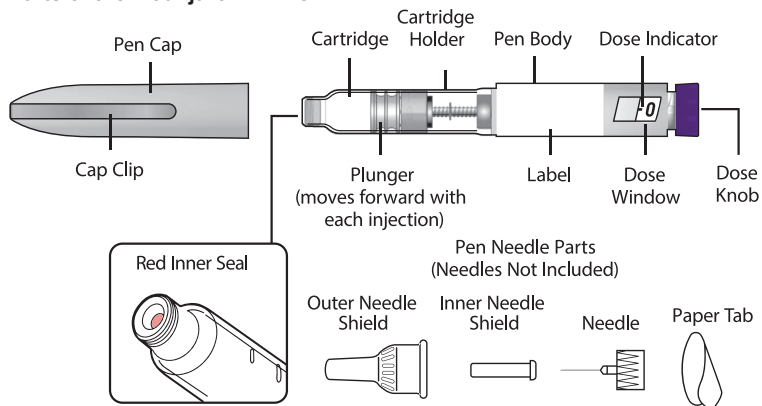


Important information you need to know before injecting Mounjaro KwikPen.

- Read this **Instructions for Use** and the package leaflet before you start injecting Mounjaro KwikPen and each time you get another new pen. There may be new information. This information does not take the place of talking to your doctor, pharmacist or nurse about your medical condition or treatment.
- Mounjaro KwikPen is a disposable multi-dose single-patient-use pre-filled pen. **The pen contains 4 fixed doses, one dose taken weekly.** Inject 0.6 ml in a single weekly injection, under the skin (subcutaneously). After 4 doses, dispose of the pen.
 - Do not share your Mounjaro KwikPen with other people, even if the pen needle has been changed.** You may give other people a serious infection or get a serious infection from them.
 - People who are blind or have vision problems should not use the pen without help from a person trained to use the pen.

Guide to parts

Parts of the Mounjaro KwikPen



Supplies needed to give your injection

- Mounjaro KwikPen
- KwikPen compatible pen needle (If you do not know what pen needle to use, talk to your healthcare professional)
- Swab
- Gauze or cotton ball
- Sharps disposal container or household container

Preparing to inject Mounjaro KwikPen

	Step 1: Wash your hands with soap and water.
	Step 2: Pull the pen cap straight off. Inspect the pen and label. Do not use if: - the medicine name or dose strength does not match your prescription. - the pen is expired (EXP) or looks damaged. - the medicine has been frozen, has particles, is cloudy, or is discoloured. Mounjaro should be colourless to slightly yellow.
	Step 3: Wipe the red inner seal with a swab.
	Step 4: Select a new pen needle. Always use a new pen needle for each injection to help prevent infections and blocked needles. Pull off the paper tab from the outer needle shield.

	Step 5: Push the capped pen needle straight onto the pen and twist the pen needle on until it is tight.
	Step 6: a. Pull off the outer needle shield and keep it. This will be reused. b. Pull off the inner needle shield. Put it in your household bin.
	Step 7: Slowly turn the dose knob until you hear 2 clicks and the 0.6 extended line is shown in the dose window. This is the prime position. It can be corrected by turning the dose knob in either direction until the prime position lines up to the dose indicator.
	Step 8: Hold your pen with the needle pointing up. Tap the cartridge holder gently to collect air bubbles at the top.
	Step 9: Release some medicine into the air by pushing the dose knob in until it stops, then slowly count to 5 while holding the dose knob. The 0.6 icon must be shown in the dose window. Do not inject into your body. Priming removes air from the cartridge and makes sure that your pen is working correctly. Your pen has been primed if a small amount of medicine comes out of the tip of the pen needle. - If you do not see medicine, repeat steps 7-9, no more than 2 additional times. - If you still do not see medicine, then change the pen needle and repeat steps 7-9, no more than 1 additional time. - If you still do not see medicine, contact your local Lilly affiliate.

Injecting Mounjaro KwikPen

	Step 10: Choose an injection site. a. You or another person can inject the medicine in your thigh or stomach (abdomen) at least 5 centimetres from the belly button. b. Another person should give you the injection in the back of your upper arm. Change (rotate) your injection site each week. You may use the same area of your body but be sure to choose a different injection site in that area.
	Step 11: Turn the dose knob until it stops and the 0.6 icon is shown in the dose window. The 0.6 icon is equal to a full 0.6 ml dose.
	Step 12: a. Insert the needle into your skin.
	b. Inject the medicine by pushing the dose knob in until it stops then slowly count to 5 while holding the dose knob. The 0.6 icon must be shown in the dose window before removing the needle.
	Step 13: Pull the needle out of your skin. A drop of medicine on the needle tip is normal. It will not affect your dose. Confirm the 0.6 icon is in the dose window. If you see the 0.6 icon in the window, you have received the full dose. If you do not see the 0.6 icon in the dose window, insert the needle back into your skin and finish your injection. Do not redial the dose. If you still do not think you received the full dose, do not start over or repeat the injection. See "Frequently asked questions" section for more information.

Needles are not included in the pack. Check with your doctor, pharmacist or nurse on the appropriate needle to use with your Mounjaro KwikPen

After your Mounjaro KwikPen injection

	Step 14: If you see blood after you pull the needle out of your skin, lightly press the injection site with gauze or a cotton ball. Do not rub the injection site.
	Step 15: Carefully replace the outer needle shield.
	Step 16: Unscrew the capped needle and put the needle in a sharps container (see "Disposing of Mounjaro KwikPen and needles" section). Do not store the pen with the needle attached to prevent leaking, blocking the needle, and air from entering the pen.
	Step 17: Replace the pen cap. Do not store the pen without the pen cap attached.

Storing your Mounjaro KwikPen

Unused pens:

- Store unused pens in the refrigerator between 2°C to 8°C.
- Unused pens may be used until the expiration date printed on the label if the pen has been kept in the refrigerator.
- Do not** freeze your pen. Throw away (discard) the pen if it has been frozen.

Used pens:

- You may store your used pen at room temperature up to 30°C after your injection.
- Keep away from heat.
- Keep your pen and needles out of the sight and reach of children.
- Dispose of the pen 30 days after first use.
- Dispose of the pen after receiving 4 weekly doses.

Disposing of Mounjaro KwikPen and pen needles

- Dispose of your used pen needles in a sharps disposal container right away after use, **do not** dispose of loose pen needles in your household waste.
- Dispose of the used pen as instructed by your healthcare professional.
- Do not recycle your used sharps disposal container.
- Ask your doctor, pharmacist or nurse about how to dispose of medicines you no longer use.

Frequently asked questions

- If you cannot remove the pen cap, gently twist the pen cap back and forth, and then pull the pen cap straight off.
- If you are unable to turn the dose knob until the 0.6 icon is in the dose window:
 - dispose of the pen, including the unused medicine. There may not be enough medicine left in the pen to give a full dose. **Do not** attempt to inject the leftover medicine.
- If the dose knob is hard to push:
 - pushing the dose knob more slowly will make it easier to inject.
 - your needle may be blocked. Put on a new pen needle and prime the pen.
 - you may have dust, food, or liquid inside the pen. Throw the pen away and get a new pen.

Additional Information:

If you have questions or problems with your Mounjaro KwikPen, contact your local Lilly affiliate or your doctor, pharmacist or nurse.

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Last revised on 18/11/2025.

Medication Calendar

Use Mounjaro 1 time a week.

I inject my weekly 0.6 ml dose on the dates below.

Write the day of the week you choose to inject. Inject on this day each week

(Example: Monday).	(Day/ Month)	(Day/ Month)	(Day/ Month)	(Day/ Month)