

Package leaflet: information for the patient

Mounjaro, 2.5 mg/dose KwikPen, solution for injection in pre-filled pen
Mounjaro, 5 mg/dose KwikPen, solution for injection in pre-filled pen
Mounjaro, 7.5 mg/dose KwikPen, solution for injection in pre-filled pen
Mounjaro, 10 mg/dose KwikPen, solution for injection in pre-filled pen
Mounjaro, 12.5 mg/dose KwikPen, solution for injection in pre-filled pen
Mounjaro, 15 mg/dose KwikPen, solution for injection in pre-filled pen
tirzepatide

This medicine is subject to additional monitoring. This allows new safety information to be identified quickly. You can help by reporting any side effects you may experience. At the end of section 4, you will read how to do this.

Read the entire package leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this package leaflet. You may need to read it again.
- Do you have any questions? Then contact your doctor, nurse, or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm them, even if their symptoms are the same as yours.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, nurse, or pharmacist.

Contents of this leaflet

1. What is Mounjaro KwikPen and what is it used for?
2. When should you not use this medicine or be extra careful with it?
3. How to use this medicine?
4. Possible side effects
5. How to store this medicine?
6. Contents of the pack and other information

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

Mounjaro contains the active substance tirzepatide and is used for the treatment of adults with type 2 diabetes mellitus. Mounjaro lowers the sugar level in the body only when the sugar level is high.

Mounjaro is also used for the treatment of adults with obesity or overweight (with a BMI of at least 27 kg/m²). Mounjaro affects the regulation of appetite, which can help you eat less food and reduce your body weight.

In type 2 diabetes, Mounjaro is used:

- as a single treatment if you cannot use metformin (another medicine for the treatment of diabetes);
- together with other medicines for the treatment of diabetes if these are not sufficient to control your blood sugar level (the amount of sugar in your blood). These can be medicines that you take orally and/or insulin that is administered via injection.

Mounjaro is also used in combination with a diet and exercise for weight loss and to maintain weight control in adults with:

- a BMI of 30 kg/m² or higher (obesity) or
- a BMI between 27 kg/m² and 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 apnea' 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.

In patients with obstructive sleep apnea (OSA) and obesity, Mounjaro can be used with or without positive airway pressure (PAP) therapy.

It is important that you continue to follow the advice you have received from your doctor, nurse, or pharmacist about diet and exercise.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the substances in this medicine. You can find these substances in section 6.

When should you be extra careful with this medicine?

Contact your doctor, nurse, or pharmacist before using this medicine if:

- you have severe problems with the digestion of food or food that stays in your stomach longer than normal (including severe gastroparesis);
- you have ever had pancreatitis (inflammation of the pancreas that can cause severe pain in the stomach and back that does not go away);
- you have a problem with your eyes (diabetic retinopathy or macular edema);
- you are using a sulfonylurea (another medicine for the treatment of diabetes) or insulin for your diabetes, as low blood sugar (hypoglycemia) may occur. Your doctor may need to adjust the dose of these other medicines to reduce this risk.

When you start treatment with Mounjaro, you may experience fluid loss/dehydration in some cases, for example, due to vomiting, nausea, and/or diarrhea. This can lead to reduced kidney function. It is important to prevent dehydration by drinking plenty of fluids. Contact your doctor if you have questions or concerns.

If you know you need to undergo surgery where you will be kept under anesthesia (sleeping), tell your doctor that you are using Mounjaro.

Children and adolescents under 18 years

This medicine should not be given to children and adolescents under 18 years, as it has not been studied in this age group.

Are you using any other medicines?

Are you using any other medicines besides Mounjaro, have you recently done so, or is there a possibility that you will use other medicines soon? Then tell your doctor, nurse, or pharmacist.

Pregnancy

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor 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.

Breastfeeding

It is not known whether tirzepatide passes into breast milk. A risk to newborns/infants cannot be excluded. If you are breastfeeding or planning to breastfeed, contact your doctor before using this medicine. You must decide with your doctor whether to stop breastfeeding or to use Mounjaro later.

Driving and using machines

It is not likely that this medicine will affect your ability to drive and use machines. However, if you use Mounjaro in combination with a sulfonylurea or insulin, low blood sugar (hypoglycemia) may occur, which can reduce your concentration. Avoid driving or using machines if you experience symptoms of low blood sugar, such as headache, drowsiness, weakness, dizziness, hunger, confusion, irritability, rapid heartbeat, and sweating (see section 4). See section 2, 'When should you be extra careful with this medicine?' for information on an increased risk of low blood sugar. Contact your doctor for more information.

Mounjaro KwikPen contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, which means it is essentially 'sodium-free'.

Mounjaro KwikPen contains benzyl alcohol

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

Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding, or if you have a liver or kidney condition. Large amounts of benzyl alcohol can accumulate in your body and cause side effects (so-called metabolic acidosis).

3. How to use this medicine?

Always use this medicine exactly as your doctor or pharmacist has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

After all doses have been correctly administered, a small amount of medicine may remain in the pen. Do not attempt to use the remaining medicine. After administering the four doses, the pen should be disposed of properly.

How much to use

The starting dose is 2.5 mg once a week for 4 weeks. After these 4 weeks, your doctor will increase your dose to 5 mg once a week.

Your doctor may increase your dose in steps of 2.5 mg to 7.5 mg, 10 mg, 12.5 mg, or 15 mg once a week, if needed. Your doctor will always tell you to stay on a certain dose for at least 4 weeks before moving to a higher dose.

Do not change your dose unless your doctor has told you to.

Choosing when to use Mounjaro

You can use your pen at any time of the day, with or without food. If possible, you should always use the pen on the same day of the week. To help remind you when to use Mounjaro, you can write it on a calendar.

If necessary, you can also change the day you inject Mounjaro weekly, as long as it has been at least 3 days since your last injection. After selecting a new administration day, continue dosing once a week on that new day.

How to inject Mounjaro KwikPen?

Mounjaro is injected under the skin (subcutaneous injection) of your abdomen – at least 5 cm away from the navel – or under the skin of your thigh or upper arm. You may need help from someone else if you want to inject into your upper arm.

If you wish, you can use the same area of your body each week. However, make sure to choose a different injection site within that area each time. If you also inject insulin, choose a different injection site for that injection.

Before using Mounjaro KwikPen, carefully read the 'User Manual' of the pen.

Testing how much sugar is in your blood (blood glucose)

If you use Mounjaro in combination with a sulfonylurea or insulin, it is important that you test your blood glucose according to the instructions of your doctor, nurse, or pharmacist (see section 2 'When should you be extra careful with this medicine?').

Have you used too much of this medicine?

If you have used more of this medicine than you should, contact your doctor immediately. Too much of this medicine can cause low blood sugar (hypoglycemia), which may make you feel nauseous or cause vomiting.

Have you forgotten to use this medicine?

If you have forgotten to inject a dose and,

it is 4 days or less since you should have injected Mounjaro, use it as soon as you remember. Then inject your next dose as usual on your normal scheduled day.

it is more than 4 days since you should have injected Mounjaro, skip the missed dose. Then inject your next dose as usual on your normal scheduled day.

Do not take a double dose to make up for a forgotten dose. There should be at least 3 days between two doses.

If you stop using this medicine

Do not stop using Mounjaro without consulting your doctor. If you stop using Mounjaro and you have type 2 diabetes, your blood sugar levels may rise.

Do you have any other questions about using this medicine? Then contact your doctor, nurse, or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects

Sometimes (occur in less than 1 in 100 users)

- Inflamed pancreas (acute pancreatitis) that can cause severe pain in the stomach and back that does not go away. You should consult a doctor immediately if you experience such symptoms.

Rarely (occur in less than 1 in 1,000 users)

- Serious allergic reactions (e.g., anaphylactic reaction, angioedema). You should seek medical help immediately and inform your doctor if you experience symptoms such as breathing difficulties, rapid swelling of the lips, tongue, and/or throat with difficulty swallowing and a rapid heartbeat.

Other side effects

Very common (occurs in more than 1 in 10 users)

- Nausea
- Diarrhea
- Stomach pain (abdominal pain) was reported in patients treated for weight management
- Vomiting was reported in patients treated for weight management
- Constipation was reported in patients treated for weight management

These side effects are usually not serious. Nausea, diarrhea, and vomiting are most common at the start of treatment with tirzepatide, but decrease over time in most patients.

- Low blood sugar (hypoglycemia) is very common when tirzepatide is used in combination with medicines that contain a sulfonylurea and/or insulin. If you are using a sulfonylurea or insulin for type 2 diabetes, the dose may need to be reduced while using tirzepatide (see section 2 'When should you be extra careful with this medicine?'). Symptoms of low blood sugar can include: headache, drowsiness, weakness, dizziness, hunger, confusion, irritability, rapid heartbeat, and sweating. Your doctor can tell you how to treat low blood sugar.

Common (occurs in up to 1 in 10 users)

- Low blood sugar (hypoglycemia), when tirzepatide is used for type 2 diabetes in combination with both metformin and a sodium-glucose co-transporter-2 inhibitor (another medicine for the treatment of diabetes)
- Allergic reaction (hypersensitivity) (e.g., rash, itching, and eczema)
- Dizziness was reported in patients treated for weight management
- Low blood pressure was reported in patients treated for weight management
- Reduced hunger (decreased appetite) was reported in patients treated for type 2 diabetes
- Abdominal pain was reported in patients treated for type 2 diabetes
- Vomiting was reported in patients treated for type 2 diabetes this usually decreases over time
- Stomach complaints (dyspepsia)
- Constipation was reported in patients treated for type 2 diabetes
- Bloating in the abdomen
- Belching (eructation)
- Flatulence

- Reflux or heartburn (also known as gastroesophageal reflux disease - GERD - a condition caused by stomach acid reaching your mouth via your esophagus)
- Hair loss was reported in patients treated for weight management
- Feeling tired (fatigue)
- Injection site reactions (e.g., itching or redness)
- Rapid pulse
- Increase in pancreatic enzymes (such as lipase and amylase) in the blood
- Increased calcitonin levels in the blood in patients treated for weight management

Sometimes (occur in less than 1 in 100 users)

- Low blood sugar (hypoglycemia), when tirzepatide is used with metformin for type 2 diabetes
- Gallstones
- Cholecystitis
- Weight loss was reported in patients treated for type 2 diabetes
- Pain at the injection site
- Increased calcitonin levels in the blood in patients treated for type 2 diabetes or for OSA with obesity
- Food and drink taste different than usual
- More or less sensation in the skin
- A delay in stomach emptying

Reporting side effects

If you experience side effects, contact your doctor, nurse, or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as mentioned in Appendix V.* By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the label of the pen and on the box after EXP. It includes a month and a year. The last day of that month is the expiry date.

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 outside the refrigerator at a temperature below 30°C for a total of 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 if the medicine is cloudy, discolored, or contains particles.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

The active substance in this medicine is tirzepatide.

Mounjaro 2.5 mg/dose KwikPen: Each dose contains 2.5 mg tirzepatide in 0.6 ml solution. Each pre-filled pen with multiple doses contains 10 mg tirzepatide in 2.4 ml (4.17 mg/ml). Each pen delivers 4 doses of 2.5 mg. Mounjaro 5 mg/dose KwikPen: Each dose contains 5 mg tirzepatide in 0.6 ml solution. Each pre-filled pen with multiple doses contains 20 mg tirzepatide in 2.4 ml (8.33 mg/ml). Each pen delivers 4 doses of 5 mg. Mounjaro 7.5 mg/dose KwikPen: Each dose contains 7.5 mg tirzepatide in 0.6 ml solution. Each pre-filled pen with multiple doses contains 30 mg tirzepatide in 2.4 ml (12.5 mg/ml). Each pen delivers 4 doses of 7.5 mg. Mounjaro 10 mg/dose KwikPen: Each dose contains 10 mg tirzepatide in 0.6 ml solution. Each pre-filled pen for multiple doses contains 40 mg tirzepatide in 2.4 ml (16.7 mg/ml). Each pen delivers 4 doses of 10 mg. Mounjaro 12.5 mg/dose KwikPen: Each dose contains 12.5 mg tirzepatide in 0.6 ml solution. Each pre-filled pen for multiple doses contains 50 mg tirzepatide in 2.4 ml (20.8 mg/ml). Each pen delivers 4 doses of 12.5 mg. Mounjaro 15 mg/dose KwikPen: Each dose contains 15 mg tirzepatide in 0.6 ml solution. Each pre-filled pen with multiple doses contains 60 mg tirzepatide in 2.4 ml (25 mg/ml). Each pen delivers 4 doses of 15 mg.

The other substances in this medicine are disodium phosphate heptahydrate (E339), benzyl alcohol (E1519) (see section 2 under: 'Mounjaro KwikPen contains benzyl alcohol' for more information), glycerol, phenol, sodium chloride, sodium hydroxide (see section 2 under: 'Mounjaro contains sodium' for more information), concentrated hydrochloric acid, and water for injections.

What does Mounjaro look like and what is in a package?

Mounjaro is a clear, colorless to light 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 an excess to prime.

Needles are not included.

Pack sizes of 1 and 3 KwikPens.

Not all pack sizes may be available in your country.

Marketing authorization holder

Eli Lilly Nederland B.V., Papendorpseweg 83, 3528 BJ Utrecht, Netherlands

Manufacturer

Eli Lilly Italia S.p.A., Via Gramsci 731/733, 50019, Sesto Fiorentino, Florence (FI), Italy

Lilly S.A., Avda. de la Industria, 30, 28108 Alcobendas, Madrid, Spain

Lilly France, 2, rue du Colonel Lilly, 67640 Fegersheim, France

Millmount Healthcare Limited, Block 7 City North Business Campus, Stamullen, K32 YD60, Ireland

Millmount Healthcare Limited, IDA Science And Technology Park, Mullagharlin, Dundalk, Co. Louth, A91 DETO, Ireland

For all information about this medicine, contact the local representative of the marketing authorization holder:

Belgium/Belgique/Belgien

Eli Lilly Benelux S.A./N.V.

Tel/Tél: + 32-(0)2 548 84 84

Lithuania

Eli Lilly Lietuva

Tel. +370 (5) 2649600

Bulgaria ТП "Ели Лили Недерланд" Б.В. - България тел. + 359 2 491 41 40	Luxembourg/Luxemburg Eli Lilly Benelux S.A./N.V. Tél/Tel: + 32-(0)2 548 84 84
Czech Republic ELI LILLY ČR, s.r.o. Tel: + 420 234 664 111	Hungary Lilly Hungária Kft. Tel: + 36 1 328 5100
Denmark Eli Lilly Danmark A/S Tlf.: +45 45 26 60 00	Malta Charles de Giorgio Ltd. Tel: + 356 25600 500
Germany Lilly Deutschland GmbH Tel. + 49-(0) 6172 273 2222	Netherlands Eli Lilly Nederland B.V. Tel: + 31-(0) 30 60 25 800
Estonia Eli Lilly Nederland B.V. Tel: +372 6 817 280	Norway Eli Lilly Norge A.S. Tel: + 47 22 88 18 00
Greece FARMASERV-LILLY S.A.B.E. Tel: +30 210 629 4600	Austria Eli Lilly Ges.m.b.H. Tel: + 43-(0) 1 20609 1270
Spain Lilly S.A. Tel: + 34-91 663 50 00	Poland Eli Lilly Polska Sp. z o.o. Tel: +48 22 440 33 00
France Lilly France Tél: +33-(0) 1 55 49 34 34	Portugal Lilly Portugal Produtos Farmacêuticos, Lda Tel: + 351-21-4126600
Croatia Eli Lilly Croatia d.o.o. Tel: +385 1 2350 999	Romania Eli Lilly Romania S.R.L. Tel: + 40 21 4023000
Ireland Eli Lilly and Company (Ireland) Limited Tel: + 353-(0) 1 661 4377	Slovenia Eli Lilly pharmaceutical company, d.o.o Tel: +386 (0)1 580 00 10
Iceland Icepharma hf. Phone + 354 540 8000	Slovak Republic Eli Lilly Slovakia s.r.o. Tel: + 421 220 663 111
Italy Eli Lilly Italia S.p.A. Tel: + 39- 055 42571	Finland Oy Eli Lilly Finland Ab Tel: + 358-(0) 9 85 45 250
Cyprus	Sweden

Phadisco Ltd
Tel: +357 22 715000

Eli Lilly Sweden AB
Tel: + 46-(0) 8 7378800

Latvia
Eli Lilly (Suisse) S.A Representation in Latvia
Tel: +371 67364000

This leaflet was last approved in

Other sources of information

More information about this medicine is available on the website of the European Medicines Agency: <http://www.ema.europa.eu>

User guide

Pre-filled pen with multiple doses

Each pen contains 4 fixed doses, one dose is injected weekly.

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Mounjaro, 15 mg/dose KwikPen, solution for injection in pre-filled pen
Tirzepatide

This user guide contains information about injecting with the Mounjaro KwikPen

Important information you need to know before injecting with the Mounjaro KwikPen.

Read this user guide and the leaflet before you start injecting with the Mounjaro KwikPen and each time you get a new pen. There may be new information. This information does not replace talking to your doctor, nurse, or pharmacist about your medical condition or treatment.

Mounjaro KwikPen is a disposable pre-filled pen with multiple doses. The pen contains 4 fixed doses, to administer one dose weekly. Inject a single injection per week, under the skin (subcutaneously).

Dispose of the pen after 4 doses, including the unused medicine. The pen is designed so that you cannot dial a full dose after you have given yourself the weekly doses 4 times. Do not inject the remaining medicine. Do not transfer the medicine from your pen into a syringe.

Do not share your Mounjaro KwikPen with others, even if a new needle is used. You could give them 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 who is trained in the use of the pen.

Guide for parts

Parts of the Mounjaro KwikPen

Cartridge-	Pen case	Dose-
Pen cap	Cartridge	holder indicator

Needle suitable for the KwikPen (if you do not know which pen needle to use, contact your healthcare provider)

Parts of the Mounjaro Kwikpen

Needle suitable for the KwikPen (if you do not know which pen needle to use, contact your healthcare provider)

What you need to administer your injection

Mounjaro KwikPen

Pen needle suitable for the KwikPen (if you do not know which pen needle to use, contact your healthcare provider)

Alcohol swab and gauze pad or cotton ball

Sharps container or household container

Preparing the injection with the Mounjaro KwikPen

Step 1:

Wash your hands with soap and water.

Step 2:

Pull the pen cap straight off.

Check the pen and the label. Do not use the pen if:

- the name of the medicine or the dose strength does not match your prescription.
- the pen is expired (EXP) or looks damaged.
- the medicine has been frozen, contains particles, is cloudy, or discolored. Mounjaro should be colorless to light yellow.

Step 3:

Wipe the red inner seal with an alcohol swab.

Step 4:

Take a new needle. Always use a new needle for each injection to prevent infections and needle blockage.

Remove the paper cover from the outer needle shield.

Step 5:

Press the needle with the cap straight onto the pen and screw the needle on tightly.

Step 6:

- a) Remove the outer needle shield and do not throw it away. You will need it later.

b) Remove the inner needle shield and discard it.

a. Outer b. Inner needle shield needle shield

Step 7:

Slowly turn the dose knob until you hear 2 clicks and the long line [-] becomes visible in the dose window. This is the position to prime your pen. This can be corrected by turning the dose knob in any direction until the long line is exactly next to the dose indicator.

Step 8:

Hold the pen upright with the needle pointing upwards.
Gently tap the cartridge holder to collect the air bubbles at the top.

Step 9:

Inject a small amount of medicine into the air by pressing the dose knob until it stops. Then slowly count to 5 while holding the dose knob down. The sign [0] must be visible in the dose window. Do not inject into your body.

By priming your pen, you remove air from the needle and the cartridge and ensure that your pen works properly. Your pen is primed when you see a little medicine at the tip of the needle.

- If you do not see any medicine, you must repeat steps 7-9, but no more than 2 times.
- If you still do not see any medicine, take a new needle and repeat steps 7-9, but no more than 1 time.
- If you still do not see any medicine, contact the local representative of Lilly who is listed in the package leaflet.

Injecting with the Mounjaro KwikPen

Step 10:

Choose a site for your injection.

- a. You or someone else can inject the medicine into your thigh or abdomen at least 5 cm away from the navel.
- b. Someone else must give the injection at the back of your upper arm.

Change your injection site every week. You can use the same area of your body, but make sure to choose a different injection site in that area.

Step 11:

Turn the dosing knob until it stops and the symbol [1] is visible in the dosing window. The symbol [1] equals a full dose.

Step 12:

a. Insert the needle into your skin.

- b. Inject the medication by pressing the dosing knob until it stops. Then count slowly to 5 while keeping the dosing knob pressed. The symbol [0] must be visible in the dose window before you remove the needle.

Step 13:

Remove the needle from your skin. A drop of medicine at the tip of the needle is normal. It does not affect your dose.

Check the symbol [0] in the dose window. If you see the symbol [0] in the dose window, you have received the full dose. If you do not see [0] in the dose window, reinsert the needle into your skin and complete your injection. Do not set a new dose. If you still think you have not received the full dose, do not start over or repeat your injection. See section 'Storing your Mounjaro KwikPen' or 'Frequently Asked Questions' for more information.

Step 14:

If you see a drop of blood after removing the needle from your skin, gently press on the injection site with a gauze pad or cotton ball. Do not rub the injection site.

Step 15:

Carefully put the outer needle shield back on the needle.

Step 16:

Twist off the needle with the cap and dispose of it in a sharps container (see 'Disposing of the Mounjaro KwikPen and pen needles').

Do not store the pen with the needle attached to prevent leakage, needle blockage, and air entering the pen.

Step 17:

Put the cap back on the pen.

Do not store the pen without the pen cap.

Storing your Mounjaro KwikPen

Unused pens:

Store unused pens in the refrigerator at 2°C to 8°C.

Pens stored in the refrigerator and not yet opened can be used until the expiration date stated on the label.

Do not store the pen in the freezer. Discard the pen if it has been frozen.

Used pens:

You can store your used pen at room temperature below 30°C after your injection.

Keep your pen and needles out of the sight and reach of children.

Discard the pen 30 days after first use, even if there is still medicine in the pen.

Discard the pen after you have received your 4 weekly doses. Attempting to inject the remaining medicine may result in an incomplete dose, even if there is still medicine in the pen.

Remaining medicine:

After completing your fourth injection, you will see some remaining medicine, and that is normal. This remaining medicine ensures the pen works correctly.

Discard the pen.

Even if there is still medicine in the pen, do not attempt to inject the remaining medicine. Attempting to inject the remaining medicine may result in an incomplete dose.

Disposal of the Mounjaro KwikPen and pen needles

Dispose of used pen needles in a sharps container or a hard plastic container with a secure lid.

Do not dispose of loose pen needles in your household trash.

Dispose of the used pen according to your healthcare provider's instructions.

Ask your healthcare provider about options for safely disposing of pens and sharps containers.

Once used, sharps containers should not be reused.

Frequently asked questions

If you have difficulty removing the pen cap, gently twist the pen cap back and forth and pull it straight off.

If you cannot turn the dose knob until you see the symbol [1] in the dose window:

- discard the pen, including the unused medicine. There may not be enough medicine left in the pen to deliver a full dose. Do not attempt to inject the remaining medicine.

If the dose knob is hard to press:

- pressing the dose knob more slowly will make injecting easier.
- your needle may be clogged. Attach a new needle and prime the pen.
- there may be dust, food, or liquid in the pen. Discard the pen and obtain a new pen.

If you have any questions or issues with your Mounjaro KwikPen, contact Lilly or consult your doctor, nurse, or pharmacist. Medication calendar

Use the Mounjaro KwikPen 1

I inject my weekly dose on the _____ times per week
dates below: _____ Write down the day of the week
you choose for the injection.

Inject every _____

Inject each week on _____

the same day (for example: _____ (day/month) (day/month) (day/month) (day/month)
Monday).

Last approved on _____