

(tirzepatide) and the KwikPen® device

> Your healthcare professional may prescribe Mounjaro:

- 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

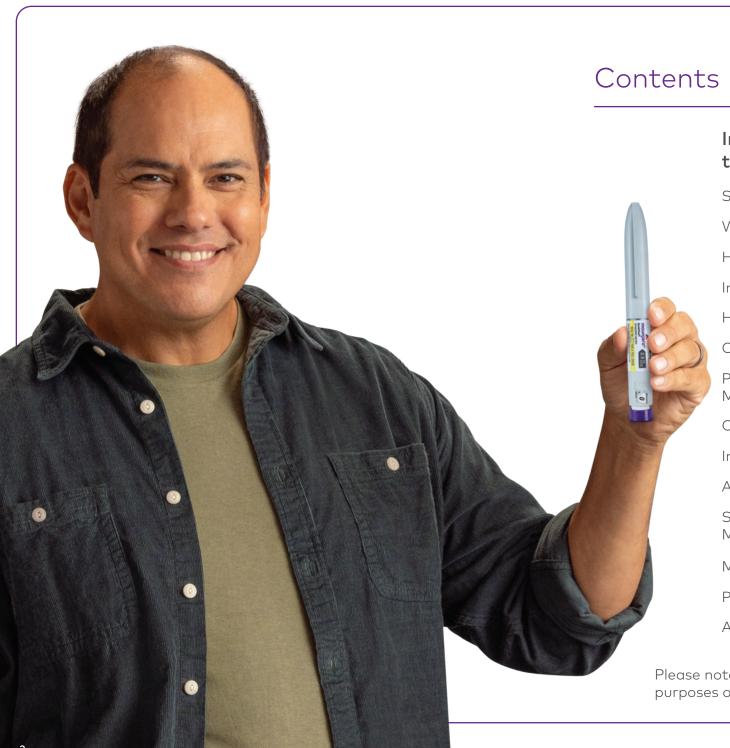
Do not use Mounjaro:

• If you are allergic to tirzepatide or any of the other ingredients of this medicine (listed in section 6 of your Patient Information Leaflet (PIL)

This information does not replace the PIL or the Instructions for Use (IFU) that accompanies your medicine. Please read the PIL and IFU carefully.

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 www.mhra.gov.uk/yellowcard for how to report side effects. Information on how to report side effects can be found on the back page. Lilly

PP-TR-GB-0342 March 2024



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Please note devices shown in this guide are for illustrative purposes only and are not actual size.

# **Setting goals**

# with your healthcare provider

In type 2 diabetes, your body does not produce enough insulin or cannot use it as well as it should, which causes sugar levels in your blood to become too high.

HbA1c (glycated haemoglobin) is a measure used to estimate how well your blood sugar has been controlled over the past 2–3 months.

Your healthcare professional will discuss your HbA1c goal with you – for most people with type 2 diabetes, the recommended range is between 48 mmol/mol and 53 mmol/mol.



Keeping your HbA1c level within range helps to reduce your risk of having complications related to diabetes.

Being overweight puts you at greater risk of serious complications, like heart disease and stroke.

Your healthcare professional may discuss your weight goal with you and the potential benefits of weight loss.



If you are overweight, weight loss, by even a small amount, may benefit your health and quality of life.

# My treatment goals

# What

# is Mounjaro

Mounjaro is a once-weekly injection used to treat adults with type 2 diabetes. It contains an active substance called **tirzepatide** (tir-zep-a-tide).

Mounjaro is not an insulin. It helps regulate blood sugar by activating the actions of 2 natural substances in your body, glucose-dependent insulinotropic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1). Mounjaro reduces the level of sugar in the body only when the levels of sugar are high.

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

Your healthcare professional may prescribe **Mounjaro along with other diabetes medications** that you already take.



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# How

# Mounjaro works

### A few of the ways Mounjaro helps your body include:



Release insulin when your blood sugar is high



Reduce how much food you eat



Slow down how quickly food leaves your stomach. This lessens over time



Regulating fat utilisation

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 this medication.

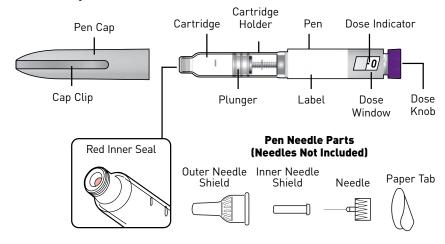
# Introducing

# the Mounjaro KwikPen

# Mounjaro KwikPen is a disposable multi-dose single-patient use prefilled pen

- Each KwikPen contains one strength of Mounjaro either 2.5 mg, 5 mg, 7.5 mg, 10 mg, 12.5 mg or 15 mg
- The pen contains 4 fixed doses, one dose taken weekly. Inject 0.6 mL in a single weekly injection

### Parts of the Mounjaro KwikPen

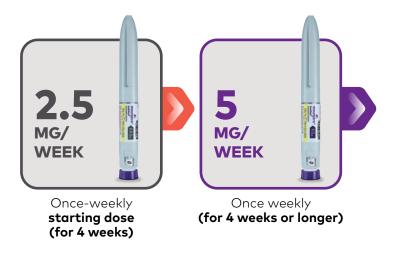


- Inject under the skin (subcutaneously) only
- You or another person can inject into your stomach (abdomen), upper leg (thigh) or upper arm
- You may need help from someone else if you want to inject in your upper arm
- Each pen is for one patient only and should not be used by anyone other than you

# How much

# Mounjaro to use

The starting dose is 2.5 mg once a week for four weeks. After four weeks your healthcare professional will increase your dose to 5 mg once a week.



Let your healthcare professional know how you're doing on the 2.5 mg and 5 mg doses during your checkup.

Your healthcare professional will decide if additional dose increases are needed.

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

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# How much

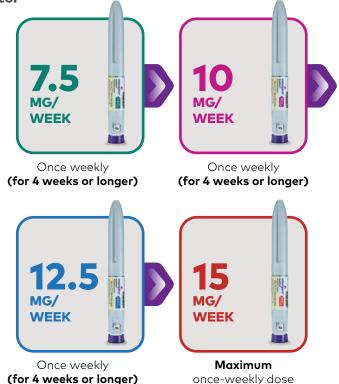
# Mounjaro to use (continued)

Each person responds differently to Mounjaro.

Your healthcare professional 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 healthcare professional 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 healthcare professional has told you to.



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# Choosing

# when to give Mounjaro



- You can use your pen at any time of the day, with or without meals
- Use Mounjaro on the same day each week
- 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 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

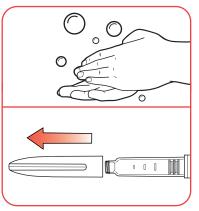
# **Preparing**

# to inject Mounjaro KwikPen

### Supplies needed to give your injection

- Mounjaro KwikPen
- KwikPen compatible needle
- Swab

- Gauze or cotton ball
- Sharps disposal container or household container



### Step 1:

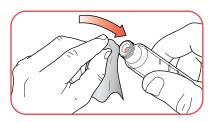
 Wash your hands with soap and water

### Step 2:

- Pull the pen cap straight off.
- Check the pen label to make sure you have the right medicine and dose, and that it has not expired
- **Inspect** the pen to make sure that it is not damaged
- Make sure the medicine is:
  - Not frozen
  - Not cloudy
  - Colourless to slightly yellow
  - Does not have particles

# **Preparing**

# to inject Mounjaro KwikPen



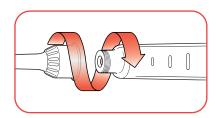
### Step 3:

• **Wipe** the red inner seal with a swab



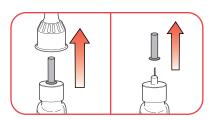
### Step 4:

- 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

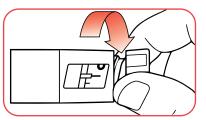


### Step 6:

- 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

# **Preparing**

# to inject Mounjaro Kwik Pen



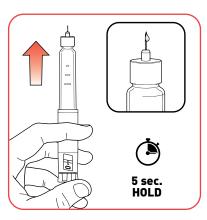
### Step 7:

2 clicks and the 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

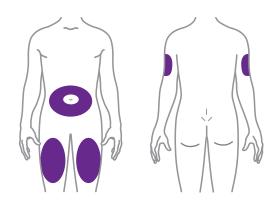


### Step 9:

- 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 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

# Choosing

# your injection site



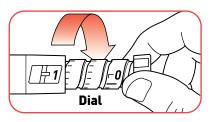
### **Step 10:**

- 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
- Check with your doctor or pharmacist if you are not sure how to use this medicine

**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. If you also inject insulin, choose a different injection site for that injection.

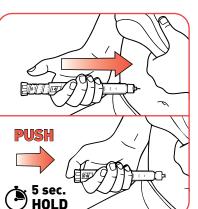
# **Injecting**

# your Mounjaro KwikPen



### Step 11:

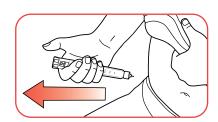
• Turn the dose knob until it stops and the 🗹 icon is shown in the dose window. The 🗇 icon is equal to a full 0.6 ml dose



### 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 ① 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 icon is in the dose window. If you see the icon in the window, you have received the full dose. If you do not see the 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. Contact your local Lilly affiliate if you have any questions or problems with 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



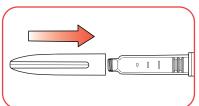
### Step 15:

• Carefully **replace** the outer needle shield



### Step 16:

 Unscrew the capped needle and put the needle in a sharps container.
 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

# Storage and disposal

of your Mounjaro KwikPen & needles

### 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. If the pen has been frozen, DO NOT USE

### 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.

# Storage and disposal

of your Mounjaro KwikPen & needles

### Disposing of Mounjaro KwikPen and 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 in your household bin or sharps disposal container after you have removed the needle
- Do not recycle your used sharps disposal container
- Ask your doctor, pharmacist or nurse about how to dispose of medicines you no longer use

### **Troubleshooting**

- If you cannot remove the pen cap, gently twist the pen cap back and forth, and then pull the pen cap straight off
- 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

# Missed a dose

# of Mounjaro?

If it's 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's 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.

### For example, if your regular dose day is Sunday:



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.

Do not stop using Mounjaro without talking with your doctor. If you stop using Mounjaro, your blood sugar levels can increase.

# **Possible**

## side effects

Like all medicines, Mounjaro can cause side effects, although not everybody gets them. Please read the PIL for a full list of side effects; some of these are listed below.

### 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)

- Low blood sugar (hypoglycaemia) when Mounjaro 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 Mounjaro. 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\*\*
- Constipation\*\*
- \*These side effects are usually not severe. They are most common when first starting Mounjaro but decrease over time in most patients
- \*\*Constipation and vomiting are very common when used for weight management, but common when used for type 2 diabetes

# **Possible**

# side effects (continued)

### 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). 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
- Stomach (abdominal) pain
- 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 pulse\*
- Increased levels of pancreatic enzymes (such as lipase and amylase\*\*) in blood
- \*Fast pulse is a common side effect when used for type 2 diabetes and uncommon when used for weight management
- \*\*Increased levels of amylase is uncommon in weight management

### Uncommon (may affect up to 1 in 100 people)

- Low blood sugar (hypoglycaemia) when Mounjaro 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
- Gallstones
- Weight loss observed in patients treated for type 2 diabetes
- Injection site pain
- · Increased calcitonin levels in blood
- Cholecystitis (infection of the gallbladder) observed in patients treated for weight management

# **Possible**

side effects (continued)

### Dehydration

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.

# **Additional**

# 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)
- 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
- You have hepatic (liver) or renal (kidney) impairment

### 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 healthcare professional 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 living with obesity or overweight and are

# **Additional**

# warnings and precautions (continued)

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 Mounjaro passes into breast milk. A risk to newborns/infants cannot be ruled out. If you are breast-feeding or are planning to breastfeed, talk to your healthcare professional before using this medicine. You and your healthcare professional 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. Talk to your healthcare professional 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

This medicine 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").

Notes

Notes	Notes

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### Any further questions?

- Speak to your healthcare professional
- Read the PIL and IFU that accompanies your medicine
- Visit: diabetes.mounjaro.co.uk



Scan the QR code to visit our website

### REPORTING SIDE EFFECTS

If you experience 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.

This information is brought to you by Lilly, the manufacturers of this medicine.

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