

Your guide to Mounjaro® ▼ (tirzepatide) and the KwikPen® device

Your healthcare professional may **prescribe Mounjaro** together **with a reduced-calorie diet and increased physical activity**:



For the treatment of adults with insufficiently controlled type 2 diabetes:

- As monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- In addition to other medicinal products for the treatment of diabetes.



For weight management, including weight loss and weight maintenance, in adults with an initial Body Mass Index (BMI*) of:

- $\geq 30 \text{ kg/m}^2$ (obesity) or
- $\geq 27 \text{ kg/m}^2$ to $< 30 \text{ kg/m}^2$ (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidaemia, obstructive sleep apnoea, cardiovascular disease, pre-diabetes, or type 2 diabetes mellitus).

*BMI is a measure of your weight in relation to your height

Do not use Mounjaro:

- If you are allergic to Mounjaro 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.

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What is Mounjaro?

Mounjaro is a once-weekly injection used for the treatment of type 2 diabetes in adults and/or weight loss, weight management. It contains an active substance called **tirzepatide** (tir-zep-a-tide).

Mounjaro activates the actions of 2 natural substances in your body, called glucose-dependent insulintrophic polypeptide (GIP) and glucagon-like peptide-1 (GLP-1).

It is important to continue to follow the advice on **diet and exercise** given to you by your healthcare professional.

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



Always use Mounjaro exactly as your prescribing healthcare professional has told you.

Check with your prescribing healthcare professional if you are not sure how to use this medication.

How

Mounjaro works

A few of the ways Mounjaro helps your body include:



Release insulin when your blood sugar is high, if you're living with T2D



Reduce how much food you eat



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



Regulating fat utilisation

How Mounjaro works if you're living with T2D



Reduces the level of sugar in the body only when the levels of sugar are high.



Improves insulin sensitivity

Mounjaro is not an insulin. Your healthcare professional may prescribe Mounjaro along with other diabetes medications that you already take.

How Mounjaro helps reduce your body weight



Regulates your appetite, giving you a sense of satiety ('fullness') & makes you feel less hungry



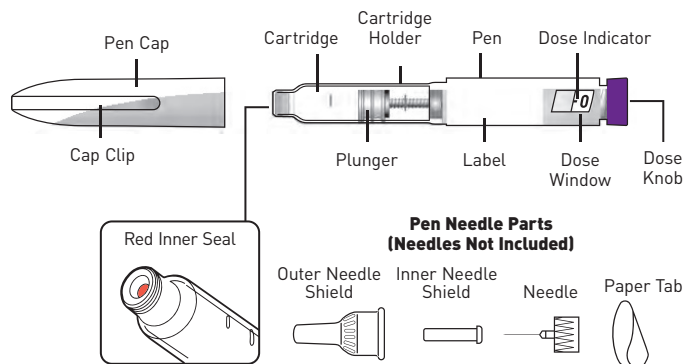
Reduces intensity of food cravings and preferences for high sugar and high fat foods.

Introducing the Mounjaro Pen

Mounjaro KwikPen is a disposable multi-dose pre-filled 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 a single weekly injection
- After 4 doses, throw away (discard) the pen, including the unused medicine.
- The pen will prevent you from dialling a full dose after you have given yourself 4 weekly doses.
- **Do not** inject the leftover medicine. Do not transfer the medicine from your pen into a syringe.

Parts of the Mounjaro KwikPen



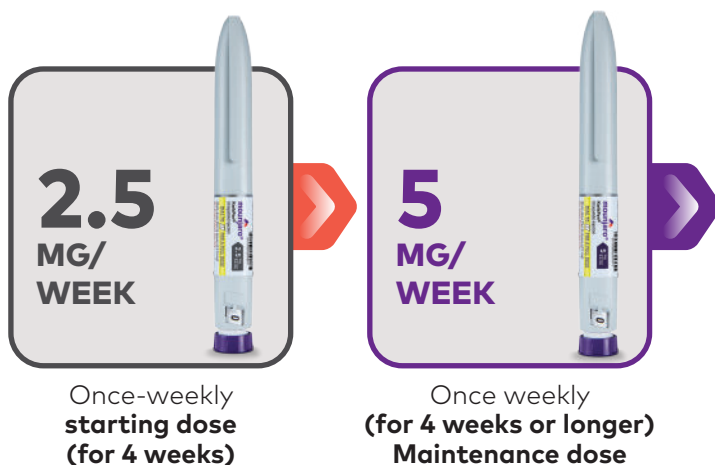
- Inject under the skin (subcutaneously) only
- You or another person can inject into your stomach (abdomen), upper leg (thigh) or upper arm
- You may need help from someone else if you want to inject in your upper arm
- Each pen is for one patient only and should not be used by anyone other than you

How much

Mounjaro to use

The starting dose is 2.5 mg once a week for 4 weeks.

After 4 weeks your prescribing 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.

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

How much

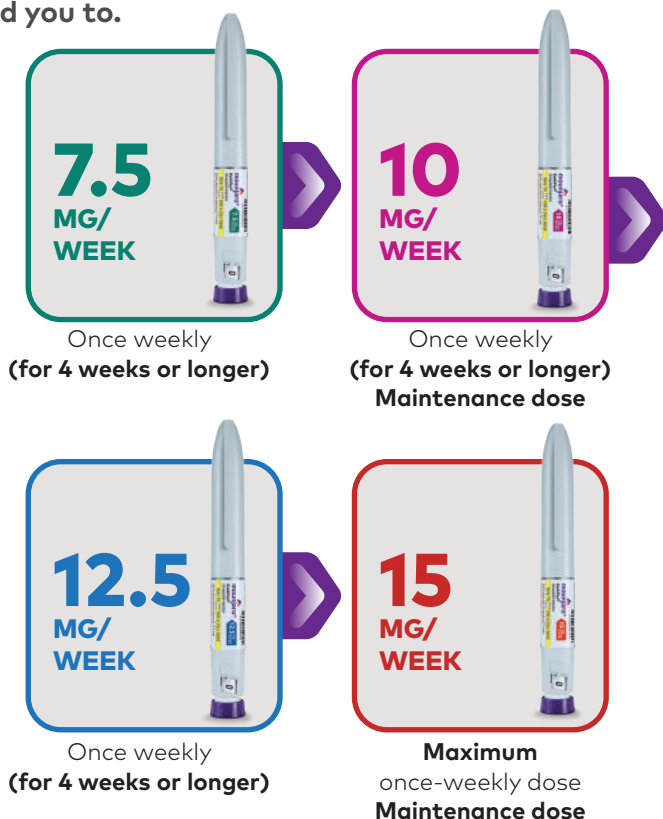
Mounjaro to use *(cont.)*

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.



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

Recommended maintenance doses are 5 mg, 10 mg, and 15 mg (maximum dose) once weekly.

Choosing when to use Mounjaro

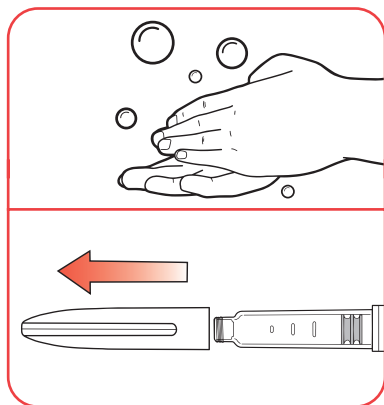


- You can use your pen at any time of the day, with or without meals
- Use Mounjaro on the **same day each week**
- To help you remember, when to use Mounjaro, you may wish to tick the day of the week when you inject your first dose on the box that your pen comes in, or mark it on a calendar.
- **If 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 with Mounjaro KwikPen

Supplies needed to give your injection

- Mounjaro KwikPen
- KwikPen compatible needle
- Swab
- Gauze or cotton ball
- Sharps disposal container or household container

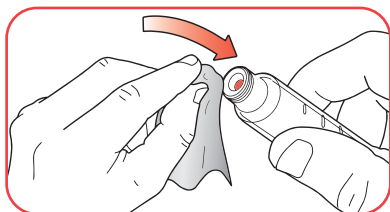


Step 1:

- **Wash** your hands with soap and water

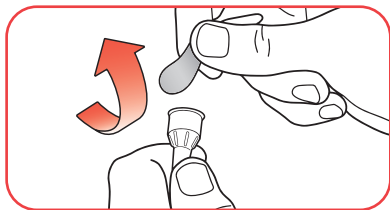
Step 2:

- 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



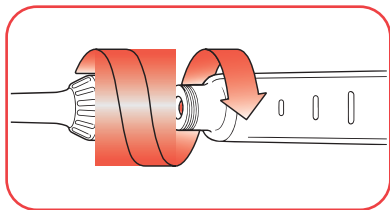
Step 3:

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



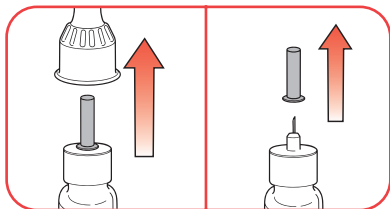
Step 4:

- **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

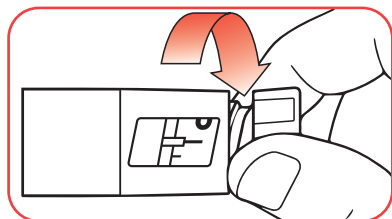


Step 6:


- Pull off the outer needle shield and **keep it**. This will be reused
- Pull off the inner needle shield. Put it in your household bin

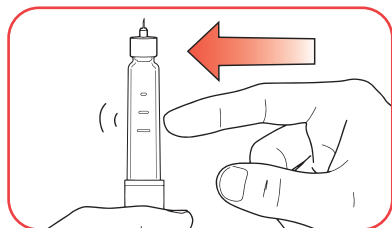
Preparing

to inject with Mounjaro KwikPen (cont.)



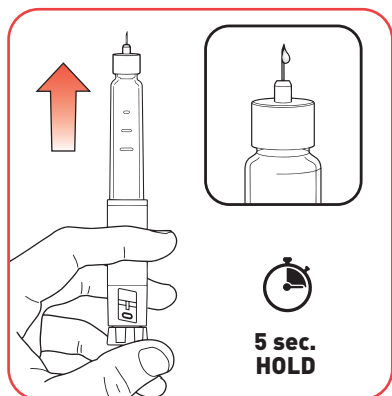
Step 7:

- **Slowly turn** the dose knob until you hear **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:

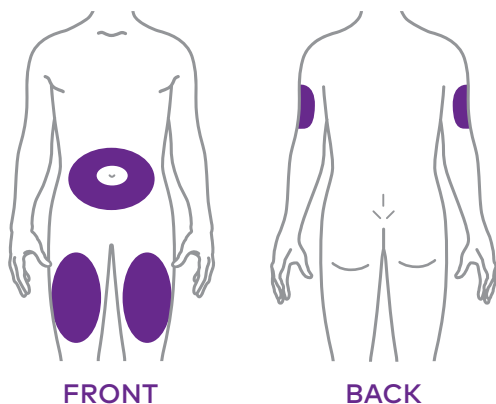
- **Hold** your pen with the needle pointing up
- **Tap** the cartridge holder gently to collect air bubbles at the top



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 listed in the patient information leaflet.

Choosing your injection site



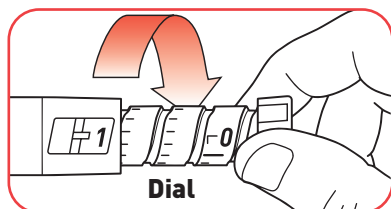
Step 10:

- Mounjaro is injected under the skin (subcutaneous injection) of your **stomach area (abdomen), or upper leg (thigh) or upper arm**
- You should seek help from someone else if you want to inject in your upper arm
- Check with your prescribing healthcare professional if you are not sure how to use this medicine

Change 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.

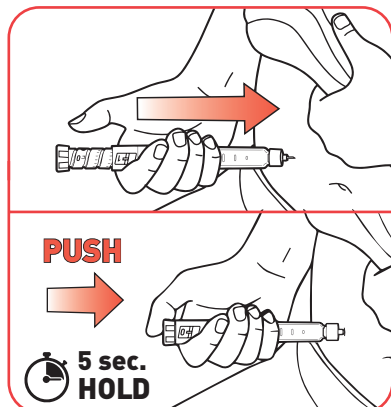
Injecting

with your Mounjaro KwikPen



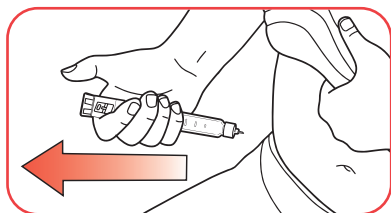
Step 11:

- Turn the dose knob until it stops and the **1** icon is shown in the dose window. The **1** icon is equal to a full dose



Step 12:

- Insert** the needle into your skin
- Inject the medicine by **pushing the dose knob in** until it stops then **slowly count to 5 while holding the dose knob**. The **0** icon must be shown in the dose window before removing the needle

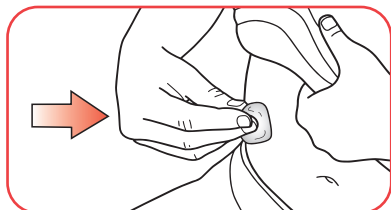


Step 13:

- **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** icon is in the dose window. If you see the **0** icon in the window, you have received the full dose. If you do not see the **0** 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 office listed in the patient information leaflet.

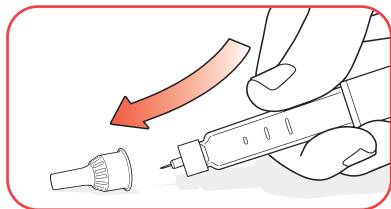
After

your Mounjaro KwikPen injection



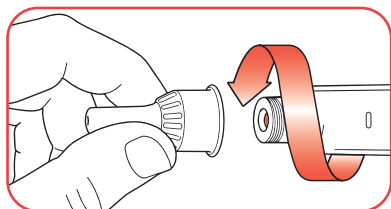
Step 14:

- 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

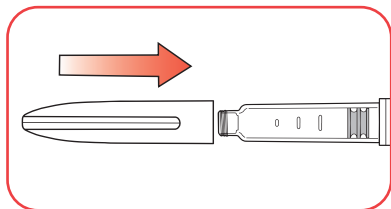


Step 16:

- 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

Needles are not included.

If you do not know what pen need to use, talk to your healthcare professional.



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

Dispose of the pen 30 days after first use even though the pen has medicine left in it.

Dispose of the pen after receiving 4 weekly doses. Attempting to inject any leftover medicine could result in an incomplete dose even though the pen still has medicine left in it.

Storage and disposal

of your Mounjaro KwikPen & needles

(cont.)

Disposing of Mounjaro KwikPen and needles



- Put your used pen needles in a sharps disposal container or a hard plastic container with a secure lid; **do not** dispose of loose pen needles in your household waste
- Dispose of the used pen as instructed by your healthcare professional.
- Ask your healthcare professional about options to dispose of the sharps disposal container properly.
- **Do not** recycle your used sharps disposal container

Commonly 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 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:

Regular dosing day	SUN ✓	MON	TUE	WED	THU	FRI	SAT
Missed dose	SUN ✗	MON ✓	TUE ✓	WED ✓	THU ✗	FRI ✗	SAT ✗
Next regular dosing day	SUN ✓	You can take <u>one</u> dose on <u>one</u> of these days			You need to skip a dose		

If you use more Mounjaro than you should, talk to your prescribing healthcare professional 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 prescribing healthcare professional. 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 prescribing healthcare professional.

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)

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

These side effects are usually not severe. 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 Mounjaro is used with medicines that contain a sulphonylurea and/or insulin. If you are using a sulphonylurea or insulin for type 2 diabetes, the dose may need to be lowered while you use Mounjaro (see section 2, 'Warnings and precautions'). Symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, feeling hungry, confusion, irritability, fast heartbeat and sweating. Your doctor should tell you how to treat low blood sugar.

Possible

side effects (*cont.*)

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 or for obstructive sleep apnoea with obesity
- Changed sense of taste

Additional

warnings and precautions

Talk to your prescribing healthcare professional 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 (diabetes medicine) or insulin, as low blood sugar (hypoglycaemia) can occur. Your healthcare professional may need to change your dose of these other medicines to reduce this risk
- You have hepatic (liver) or renal (kidney) impairment
- You know that you are due to have surgery where you will be under anesthesia (sleeping)



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 prescribing healthcare professional if you have any questions or concerns.

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 prescribing healthcare professional if you are using, have recently used or might use any other medicines.

Pregnancy

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.

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 prescribing healthcare professional before using this medicine. You and your healthcare professional should decide if you should stop breast feeding or delay using Mounjaro.

Additional

warnings and precautions (*cont.*)

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 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").

Tips if experiencing Gastrointestinal (GI) symptoms

As with all medicines, you may feel side effects with Mounjaro¹.

The **most frequently** reported side effects in a Mounjaro's clinical trials were **gastrointestinal disorders, including nausea, diarrhoea, constipation, and vomiting¹.**

In general, these reactions were mostly mild or moderate in severity and occurred often during dose escalation and decreased over time¹.

Tips for managing GI symptoms:



Eating smaller portions more frequently



Being mindful to stop eating once full



Avoiding eating when not hungry



Staying hydrated



Avoiding high-fat or spicy food



Moderating intake of alcohol and fizzy drinks (particularly in the context of nausea and dyspepsia)

If your symptoms continue, speak with your healthcare provider.

Why not track your progress?



Starting Body Weight:.....



Starting waist circumference.....



Starting HbA1c, if you're living with T2D:.....

What are you other treatment goals?

To help you remember when to use Mounjaro, consider marking the day of the week you inject your dose on this calendar.

You can track your progress by logging your result.

Month 1							Weight
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	

Month 2							Weight
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	

Why not track your progress?

(cont.)

Month 3							Weight	HbA1c
SUN	MON	TUE	WED	THU	FRI	SAT		
SUN	MON	TUE	WED	THU	FRI	SAT		
SUN	MON	TUE	WED	THU	FRI	SAT		
SUN	MON	TUE	WED	THU	FRI	SAT		

Month 4							Weight
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	

Month 5							Weight
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	
SUN	MON	TUE	WED	THU	FRI	SAT	

Month 6							Weight	HbA1c
SUN	MON	TUE	WED	THU	FRI	SAT		
SUN	MON	TUE	WED	THU	FRI	SAT		
SUN	MON	TUE	WED	THU	FRI	SAT		
SUN	MON	TUE	WED	THU	FRI	SAT		

Notes

This image shows a single sheet of white paper with horizontal blue ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

Notes

Notes

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Notes

Where to learn more:

- Speak to your prescribing healthcare professional
- Read the PIL and IFU that come with your medicine



For a step-by-step video showing you how to use your Mounjaro Kwikpen, visit www.kaltura.com/tiny/d5c1g

REPORTING SIDE EFFECTS

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 can also report side effects directly via Ireland: HPRA Pharmacovigilance, website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

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

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