Package leaflet: Information for the patient

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 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.

What is in this leaflet

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[1*]
- Stomach (abdominal) pain[1]
- Constipation[1].

[*]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 pulse[1]
- Increased levels of pancreatic enzymes (such as lipase and amylase[2]) in blood
- Increased calcitonin levels in blood[3]
- Gallstones[3]

[1]Fast pulse is a common side effect when used for type 2 diabetes and uncommon when used for weight management.
[2]Increased levels of amylase is uncommon in weight management.
[3]Increased 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 ºC 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.

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 0.6ml 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 sizes of 1 and 3 pre-filled KwikPens. Not all pack sizes may be available in your country.

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