

# MOUNJARO SOLUTION FOR INJECTION IN PRE-FILLED PEN

Tirzepatide (2.5mg, 5mg, 7.5mg, 10mg, 12.5mg and 15mg)

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## What Mounjaro is used for

Mounjaro an injectable prescription medicine for adults that contains an active substance called tirzepatide and is used to treat adults with type 2 diabetes mellitus.

Type 2 diabetes is a condition in which your body does not make enough insulin, and the insulin that your body produces does not work as well as it should.

When this happens, sugar (glucose) builds up in the blood. Effective treatment of diabetes, with good control of blood sugar, prevents long-term complications from your diabetes.

Mounjaro is used:

- on its own if your blood sugar is not properly controlled by diet and exercise alone, and you can't take metformin (another diabetes medicine).

- or 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.

## How Mounjaro works

Mounjaro controls blood sugar levels along with diet and exercise

## Before you use Mounjaro

- When you must not use it

- If you are allergic to tirzepatide or any of the other ingredients of this medicine

- Before you start to use it

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 causes severe pain in the stomach and back which does not go away.

- if you have a problem with your eyes (diabetic retinopathy or macular oedema).

- you are taking a *sulphonylurea* 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.

## Mounjaro contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. This is because Mounjaro can affect the way some other medicines work. Also, some medicines can affect the way Mounjaro works.

Tell your doctor if you are taking any of the following medicine:

- Oral contraceptives (family planning medicines)

## How to use Mounjaro

Mounjaro is injected under the skin (subcutaneous injection) of your stomach area (abdomen) or upper leg (thigh). If the injection is given by someone else, they may 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.

- How much to use

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.

The starting dose is 2.5 mg once a week for four weeks. After four weeks your doctor should increase your dose to 5 mg once a week.

Your doctor may increase your dose to 7.5 mg, 10 mg, 12.5 mg or 15 mg once a week if you need it. In each case you should 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.

- When to use it

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, 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 on a calendar.

- How long to use it

Continue taking Mounjaro for as long as your doctor recommends.

It is important that you test your blood glucose levels as instructed by your doctor, pharmacist or nurse, if you are taking Mounjaro with a sulphonylurea or insulin.

- If you forget to use it

If you forget to inject a dose and,

- it is 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 is 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.

You can also change the day of the week on which you inject Mounjaro if necessary, as long as the time between two doses is at least 3 days (72 hours).

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## - If you use too much (overdose)

If you use more Mounjaro than you should talk to your doctor immediately. Too much of this medicine may make your blood sugar too low (*hypoglycaemia*) and can make you feel sick or be sick.

## **While you are using Mounjaro**

### - Things you must do

Tell all the doctors, dentists and pharmacists treating you that you are taking MOUNJARO.

Tell your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

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

Do not take any new medicines without consulting your doctor.

Do not give MOUNJARO to anyone else, even if they have the same symptoms or condition as you.

### - Things to be careful of

When initiating treatment with Mounjaro, you may in some cases experience loss of fluids/dehydration, e.g. in case of 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.

### *Pregnancy and breast-feeding*

If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. It is preferable to avoid the use of Mounjaro in pregnancy as the effects of this medicine in pregnant women are not known.

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 breast feed or use Mounjaro.

### *Driving and using machines*

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.

See section 'Warning and precautions' in the package insert for information on increased risk of low blood sugar and for the warning signs of low blood sugar.

Talk to your doctor for further information.

## **Side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

### ***Very common (may affect more than 1 in 10 people)***

- Feeling sick (nausea)
- Diarrhoea

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

- Low blood sugar (*hypoglycaemia*) is very common when tirzepatide is used with medicines that contain a sulphonylurea and/or insulin. If you are taking a sulphonylurea or insulin, the dose may need to be lowered while you use tirzepatide.

- 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.

### ***Common (may affect up to 1 in 10 people)***

- Low blood sugar (*hypoglycaemia*) is common when tirzepatide is used with both metformin and a sodium-glucose co transporter 2 inhibitor.

- Feeling less hungry (decreased appetite)
- Stomach (abdominal) pain.
- Being sick (vomiting) – this usually goes away over time
- Indigestion (*dyspepsia*),
- Constipation
- 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
- Feeling tired
- Injection site reactions (e.g. rash or redness)

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

Low blood sugar (*hypoglycaemia*) is uncommon when tirzepatide is used with metformin.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [**Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)**].

## **Storage and Disposal of Mounjaro**

### - Storage

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. If the pen has been frozen, **DO NOT USE**.

Store in the original packaging in order to protect from light.

Mounjaro can be stored unrefrigerated not above 30 °C for up to 21 days.

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 use this medicine after the expiry date which is stated on the carton and the pen after the expiration date.

The expiry date refers to the last day of that month.

### - Disposal

Do not throw away any medicines via

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wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## Product Description

### - What it looks like

Mounjaro is a clear, colourless to slightly yellow, solution for injection in a pre-filled pen.

Each pre-filled pen contains 0.5 ml solution.

**The pre-filled pen is for single use only.**

Pack sizes of 2, 4 or multipacks of 12 (3 packs of 4) pre-filled pens. Not all pack sizes may be available in your country.

### - Ingredients

#### - **Active ingredient:**

The active substance is *tirzepatide*.

- Mounjaro 2.5 mg: Each pre-filled pen contains 2.5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro 5 mg: Each pre-filled pen contains 5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro 7.5 mg: Each pre-filled pen contains 7.5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro 10 mg: Each pre-filled pen contains 10 mg of tirzepatide in 0.5 ml solution.
- Mounjaro 12.5 mg: Each pre-filled pen contains 12.5 mg of tirzepatide in 0.5 ml solution.
- Mounjaro 15 mg: Each pre-filled pen contains 15 mg of tirzepatide in 0.5 ml solution.

### - **Inactive ingredients**

The other ingredients are:

The other ingredients are sodium phosphate dibasic heptahydrate, sodium chloride, sodium hydroxide (see section *before you start to use it* under 'Mounjaro contains sodium' for further information); hydrochloric acid and water for injections.

### - MAL number

Mounjaro 2.5 mg solution for injection in pre-filled pen – MALXXXXXXXX

Mounjaro 5 mg solution for injection in pre-filled pen – MALXXXXXXXX

Mounjaro 7.5 mg solution for injection in pre-filled pen – MALXXXXXXXX

Mounjaro 10 mg solution for injection in pre-filled pen – MALXXXXXXXX

Mounjaro 12.5 mg solution for injection in pre-filled pen – MALXXXXXXXX

Mounjaro 15 mg solution for injection in pre-filled pen – MALXXXXXXXX

## Manufacturer

Eli Lilly and Company  
Lilly Corporate Center,  
Indianapolis,  
Indiana 46285, USA

## Product Registration Holder

Zuellig Pharma Sdn Bhd  
No. 15 Persiaran Pasak Bumi,  
Seksyen U8, Perindustrian Bukit  
Jelutong, 40150 Shah Alam,  
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## Date of Revision

10/08/2023

## Serial Number

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