

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMOUNJARO®

tirzepatide injection

Read this carefully before you start taking MOUNJARO and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about MOUNJARO.

Serious Warnings and Precautions

- Tirzepatide, the medicinal ingredient in MOUNJARO, increased the risk of developing thyroid C-cell tumors in rats. It is not known if the risk seen in rats applies to humans. It is uncertain if MOUNJARO may increase your risk for developing thyroid C-cell tumors, including medullary thyroid carcinoma.
- Do not use MOUNJARO if you:
 - have a personal or family history of Medullary Thyroid Cancer (MTC);
 - have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Your healthcare professional will speak to you about the risk and symptoms of thyroid tumors.

What is MOUNJARO used for?

MOUNJARO is used along with diet and exercise to:

- improve blood sugar levels in adults with type 2 diabetes.

MOUNJARO is used:

- alone, if you cannot take metformin;
- with metformin;
- with metformin and a sulfonylurea;
- with metformin and a sodium-glucose cotransporter 2 inhibitor (SGLT2i);
- with basal insulin (with or without metformin).

How does MOUNJARO work?

MOUNJARO belongs to a class of medicines called GIP and GLP-1 receptor agonists. MOUNJARO lowers your blood sugar by helping your body release more insulin when your blood sugar is high. It also reduces levels of glucagon, a hormone that prevents blood sugar from decreasing too much.

What are the ingredients in MOUNJARO?

Medicinal ingredients: tirzepatide

Non-medicinal ingredients: Hydrochloric acid solution, sodium chloride, sodium hydroxide solution, sodium phosphate dibasic heptahydrate, water for injection.

MOUNJARO comes in the following dosage forms:

Solution in a single-dose prefilled pen or a single-dose vial in the following strengths: 2.5 mg/0.5 mL, 5 mg/0.5 mL, 7.5 mg/0.5 mL, 10 mg/0.5 mL, 12.5 mg/0.5 mL, or 15 mg/0.5 mL.

Do not use MOUNJARO if:

- you are allergic to tirzepatide or to any ingredient in MOUNJARO or component of its container.
- you or a member of your family has ever had Medullary Thyroid Cancer (MTC).
- you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2)
- you are pregnant or breast-feeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MOUNJARO. Talk about any health conditions or problems you may have, including if you have:

- type 1 diabetes.
- a heart condition that causes an increase in heart rate.
- experienced severe allergic reactions and swelling when taking GLP-1 receptor agonist medicines.
- ever had diabetic ketoacidosis (increased ketones in the blood or urine).
- severe problems with your stomach (gastroparesis) or food digestion. MOUNJARO slows stomach emptying so food passes more slowly through your stomach.

Other warnings you should know about:*Gallbladder Disease*

- You may suddenly develop symptoms of gallbladder disease when taking MOUNJARO.
- Gallbladder disease can include inflammation of the gallbladder (cholecystitis), or gallstones blocking the bile duct (biliary colic).
- Symptoms may include sudden and intensifying pain in your abdomen, between your shoulder blades or your right shoulder. You should seek immediate medical attention if you experience severe abdominal pain, yellowing of your skin, or high fever with chills. If you think you might have a problem with your gallbladder, consult your healthcare professional.

Children and adolescents

MOUNJARO is not recommended in children and adolescents under 18 years.

Pregnancy and breast-feeding

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- You should not take MOUNJARO if you are pregnant. It may harm your unborn baby.
- If you are able to become pregnant:
 - Avoid becoming pregnant while you are taking MOUNJARO. Use effective birth control during treatment and at least one month after your last dose. If you are using oral hormonal drugs as a birth control method:
 - Switch to a non-oral hormonal birth control medicine. Or;
 - Add a barrier method of birth control (e.g., condoms). Use this method for 4 weeks when beginning treatment with MOUNJARO and for 4 weeks after each time your dose is increased.
- Do not breastfeed while you are taking MOUNJARO.

Driving and using machines

- Low blood sugar (hypoglycemia) may affect your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar.

- See “What are possible side effects from using MOUNJARO” for the warning signs of low blood sugar. Talk to your doctor for further information.

Pancreas problems

- Taking MOUNJARO can cause an inflamed pancreas (acute pancreatitis).
- Speak to your healthcare professional if you have or have had pancreas problems such as inflammation of the pancreas.
- Your healthcare professional will monitor you for any symptoms of acute pancreatitis. Speak to your healthcare professional immediately if you have severe and on-going pain in the stomach area. See “What are possible side effects from using MOUNJARO” for more symptoms of acute pancreatitis.

Serious allergic reactions

- Stop using MOUNJARO and get medical help right away if you have any symptoms of a serious allergic reaction. This can include itching, rash, or difficulty breathing. See “What are possible side effects from using MOUNJARO” for more symptoms of an allergic reaction.

Blood tests

- Your blood sugar levels should be monitored at the start of treatment if you are taking MOUNJARO with anti-diabetic medicines known as sulfonylurea or insulin. Monitoring your blood sugar levels will help reduce the risk of developing hypoglycemia (low blood sugar).
- *Your Healthcare professional will monitor your blood sugar levels periodically during your treatment with MOUNJARO.*

Kidney problems

- During treatment with MOUNJARO, you may experience feeling sick (nausea) or being sick (vomiting), and diarrhea. These side effects can cause dehydration (loss of fluids). Dehydration can lead to problems with your kidneys, such as sudden kidney failure.
- It is therefore important to drink plenty of fluids to prevent dehydration.
- Talk to your healthcare professional if you have any questions or concerns.

Diabetic eye disease (retinopathy)

- Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. This may require treatment or lead to a loss of vision.
- You should inform your doctor if you have diabetic eye disease (retinopathy) or if you experience vision problems during treatment with MOUNJARO.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MOUNJARO:

- oral birth control medicines
- anti-diabetic medicines known as a sulfonylurea (e.g., glyburide, gliclazide, glimepiride) or insulin. Combining these medicines with MOUNJARO might increase the risk of getting low blood sugar. Your healthcare professional may tell you to lower your regular dose of these drugs when adding MOUNJARO treatment.
- medicines that may increase your heart rate.

How to take MOUNJARO:

- Take MOUNJARO exactly as your healthcare professional has prescribed. Do not change your dose or stop taking MOUNJARO without talking to your healthcare professional.
- Set a reminder on a calendar to remind yourself of your weekly dose.

- The pen and vial have glass parts. Handle carefully. If you drop the pen or vial on a hard surface, do not use it. Use a new pen or vial for your injection.
- An Instructions for Use leaflet is enclosed with the MOUNJARO Pen or vial. Read the Instructions for Use leaflet for instructions on how to use the MOUNJARO pen or vial.
- Talk to your healthcare provider about how to correctly administer MOUNJARO before you use it for the first time. If you do not understand the instructions or have any questions, talk with your doctor, diabetes nurse, or pharmacist.
- You can give yourself the injection at any time of the day, with or without food.

How to inject MOUNJARO:

- MOUNJARO is an injection which is given under the skin (subcutaneously). Do not inject MOUNJARO into a vein or muscle.
- The best places to give yourself the injection are your stomach area (abdomen) or upper leg (thigh). Another person should give you the injection in the back of your upper arm.
- Do not use the same site for each injection. Change (rotate) your injection site with each weekly injection.

Your dose of MOUNJARO may change depending on:

- if you are taking other diabetic medication
- your physical health (e.g., weight, illness, physical activity)
- your diet

Changing the day of your weekly injection:

- If necessary, you can change the day of your weekly injection. There has to be at least 3 days since your last injection of MOUNJARO.

If you give yourself insulin in addition to MOUNJARO:

- never mix both medications (Insulin and MOUNJARO) in the same container. Give yourself separate injections of insulin and MOUNJARO.
- You may give both injections in the same body area (for example, your stomach area), but not right next to each other.

Usual adult dose:

- The recommended starting dose is 2.5 mg administered once weekly subcutaneously (under the skin). After 4 weeks your dose will go up to 5 mg once weekly. If needed, the dose may be increased by 2.5 mg after at least 4 weeks on your current dose. The maximum recommended dose is 15 mg once weekly.

Overdose:

If you think you, or a person you are caring for, have taken too much MOUNJARO, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

If you miss a dose and:

- it has been 4 days (96 hours) or less since you should have used MOUNJARO, use it as soon as you remember. Then inject your next dose on your usual scheduled day.
- it has been more than 4 days (96 hours) since you should have used MOUNJARO, skip the missed dose. Then inject your next dose on your usual scheduled day.

What are possible side effects from using MOUNJARO?

These are not all the possible side effects you may have when taking MOUNJARO. If you experience any side effects including side effects not listed here, tell your healthcare professional.

- Belching
- Bloating of the stomach
- Constipation
- Decreased appetite
- Diarrhea
- Feeling tired
- Gas (flatulence)
- Increased heart rate
- Indigestion
- Injection site reactions – such as bruising, pain, irritation, itching, and rash
- Nausea
- Reflux or heart burn – also called gastro-esophageal reflux disease
- Stomach pain
- Vomiting
- Weight loss

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Diabetic eye disease (Diabetic retinopathy): blurred vision, lines in vision		✓	
UNCOMMON			
Severe low blood sugar (hypoglycemia): disorientation, loss of consciousness, or seizure		✓	
RARE			
Pancreatitis: prolonged severe abdominal pain with or without vomiting		✓	✓
Dehydration that can cause sudden kidney failure: dark yellow and strong-smelling pee, feeling extremely thirsty, feeling dizzy or lightheaded		✓	✓
Sudden gallbladder problems: severe abdominal pain,		✓	✓

yellowing of your skin, or high fever with chills			
UNKNOWN			
Serious allergic reaction (anaphylactic reaction, angioedema): breathing problems, swelling of the throat and face, fast heartbeat		✓	✓

If you have a troublesome symptom or side effect, including symptoms or side effects that are not listed here, or a side effect becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- Store MOUNJARO in a refrigerator at 2°C to 8°C.
- If needed, each single-dose pen or single-dose vial can be stored at room temperature below 30°C for up to a total of 21 days.
- Do not freeze MOUNJARO. Do not use MOUNJARO if frozen. If the pen or vial has been frozen, throw it away and use a new pen or vial.
- Store MOUNJARO in the original carton to protect from light.
- Keep out of reach and sight of children.
- Throw away all opened vials after use, even if there is medicine left in the vial.

If you want more information about MOUNJARO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website www.lilly.ca, or by calling 1-888-545-5972.

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This leaflet was prepared by Eli Lilly Canada, Inc.

Last Revised NOV 01, 2023

MOU-0003-PM-20231101