

Medication Guide
MOUNJARO® [mown-JAHR-OH]
(tirzepatide)
injection, for subcutaneous use

What is the most important information I should know about MOUNJARO?

MOUNJARO may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats, MOUNJARO and medicines that work like MOUNJARO caused thyroid tumors, including thyroid cancer. It is not known if MOUNJARO will cause thyroid tumors, or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use MOUNJARO if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

What is MOUNJARO?

- MOUNJARO is an injectable prescription medicine that is used along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes mellitus.
- It is not known if MOUNJARO can be used in people who have had pancreatitis.
- MOUNJARO is not for use in people with type 1 diabetes.
- It is not known if MOUNJARO is safe and effective for use in children under 18 years of age.

Do not use MOUNJARO if:

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you have had a serious allergic reaction to tirzepatide or any of the ingredients in MOUNJARO. See the end of this Medication Guide for a complete list of ingredients in MOUNJARO.

Before using MOUNJARO, tell your healthcare provider about all of your medical conditions, including if you:

- have or have had problems with your pancreas or kidneys.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have a history of diabetic retinopathy.
- are pregnant or plan to become pregnant. It is not known if MOUNJARO will harm your unborn baby. Tell your healthcare provider if you become pregnant while using MOUNJARO.
 - **Birth control pills by mouth may not work as well while using MOUNJARO.** If you take birth control pills by mouth, your healthcare provider may recommend another type of birth control for 4 weeks after you start MOUNJARO and for 4 weeks after each increase in your dose of MOUNJARO. Talk to your healthcare provider about birth control methods that may be right for you while using MOUNJARO.
- are breastfeeding or plan to breastfeed. It is not known if MOUNJARO passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby while using MOUNJARO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. MOUNJARO may affect the way some medicines work, and some medicines may affect the way MOUNJARO works.

Before using MOUNJARO, tell your healthcare provider if you are taking other medicines to treat diabetes including insulin or sulfonylureas which could increase your risk of low blood sugar. Talk to your healthcare provider about low blood sugar and how to manage it.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use MOUNJARO?

- Read the **Instructions for Use** that comes with MOUNJARO.
- Use MOUNJARO exactly as your healthcare provider tells you to. A healthcare provider should show you how to prepare and inject your dose of MOUNJARO before injecting for the first time.
- MOUNJARO is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm.
- **Use MOUNJARO 1 time each week, at any time of the day.**
- You may change the day of the week you use MOUNJARO as long as the time between the 2 doses is at least **3 days (72 hours)**.
- If you miss a dose of MOUNJARO, take the missed dose as soon as possible within 4 days (96 hours) after the missed dose. If more than 4 days have passed, skip the missed dose and take your next dose on the regularly scheduled day. **Do not** take **2** doses of MOUNJARO within **3** days of each other.
- MOUNJARO may be taken with or without food.
- **Do not** mix insulin and MOUNJARO together in the same injection.
- You may give an injection of MOUNJARO and insulin in the same body area (such as your stomach area), but not right next to each other.
- Change (rotate) your injection site with each weekly injection. **Do not** use the same site for each injection.
- If you take too much MOUNJARO, call your healthcare provider.

What are the possible side effects of MOUNJARO?

MOUNJARO may cause serious side effects, including:

- See **“What is the most important information I should know about MOUNJARO?”**
- **inflammation of your pancreas (pancreatitis).** Stop using MOUNJARO and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use MOUNJARO with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. **Signs and symptoms of low blood sugar may include:**
 - dizziness or light-headedness
 - blurred vision
 - anxiety, irritability, or mood changes
 - sweating
 - slurred speech
 - hunger
 - confusion or drowsiness
 - shakiness
 - weakness
 - headache
 - fast heartbeat
 - feeling jittery
- **serious allergic reactions.** Stop using MOUNJARO and get medical help right away if you have any symptoms of a serious allergic reaction including:
 - swelling of your face, lips, tongue or throat
 - fainting or feeling dizzy
 - problems breathing or swallowing
 - very rapid heartbeat
 - severe rash or itching
- **kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse. It is important for you to drink fluids to help reduce your chance of dehydration.
- **severe stomach problems.** Stomach problems, sometimes severe, have been reported in people who use MOUNJARO. Tell your healthcare provider if you have stomach problems that are severe or will not go away.
- **changes in vision.** Tell your healthcare provider if you have changes in vision during treatment with MOUNJARO.
- **gallbladder problems.** Gallbladder problems have happened in some people who use MOUNJARO. Tell your healthcare provider right away if you get symptoms of gallbladder problems which may include:
 - pain in your upper stomach (abdomen)
 - yellowing of skin or eyes (jaundice)
 - fever
 - clay-colored stools

The most common side effects of MOUNJARO include:

- nausea
- diarrhea
- decreased appetite
- vomiting
- constipation
- indigestion
- stomach (abdominal) pain

Talk to your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of MOUNJARO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store MOUNJARO?

- Store MOUNJARO in the refrigerator between 36°F to 46°F (2°C to 8°C). Store MOUNJARO in the original carton until use to protect it from light.
- If needed, each single-dose pen or single-dose vial can be stored at room temperature up to 86°F (30°C) for up to 21 days.
- Do not freeze MOUNJARO. Do not use MOUNJARO if frozen.

Keep MOUNJARO and all medicines out of the reach of children.

General information about the safe and effective use of MOUNJARO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use MOUNJARO for a condition for which it was not prescribed. Do not give MOUNJARO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about MOUNJARO that is written for health professionals.

What are the ingredients in MOUNJARO?

Active ingredient: tirzepatide

Inactive ingredients: sodium chloride, sodium phosphate dibasic heptahydrate, and water for injection. Hydrochloric acid solution and/or sodium hydroxide solution may have been added to adjust the pH.

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For more information, go to www.MOUNJARO.com or call 1-800-545-5979.