

**MEDICATION GUIDE**  
**TRADJENTA® (TRAD gen ta)**  
**(linagliptin tablets)**  
**for oral use**

Read this Medication Guide carefully before you start taking TRADJENTA and each time you get a refill. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment. If you have any questions about TRADJENTA, ask your doctor or pharmacist.

**What is the most important information I should know about TRADJENTA?**

**TRADJENTA can cause serious side effects, including:**

- **Inflammation of the pancreas (pancreatitis)** which may be severe and lead to death. Certain medical problems make you more likely to get pancreatitis.

**Before you start taking TRADJENTA, tell your doctor if you have ever had:**

- inflammation of your pancreas (pancreatitis)
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

Stop taking TRADJENTA and call your doctor right away if you have pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

- **Heart failure.** Heart failure means your heart does not pump blood well enough.

**Before you start taking TRADJENTA, tell your doctor if you have ever had heart failure or have problems with your kidneys.** Contact your doctor right away if you have any of the following symptoms:

- increasing shortness of breath or trouble breathing, especially when you lie down
- swelling or fluid retention, especially in the feet, ankles or legs
- an unusually fast increase in weight
- unusual tiredness

These may be symptoms of heart failure.

**What is TRADJENTA?**

- TRADJENTA is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- TRADJENTA is not for people with type 1 diabetes.
- TRADJENTA is not for people with diabetic ketoacidosis (increased ketones in the blood or urine).
- If you have had pancreatitis in the past, it is not known if you have a higher chance of getting pancreatitis while you take TRADJENTA.
- It is not known if TRADJENTA is safe and effective in children under 18 years of age.

**Who should not take TRADJENTA?**

**Do not take TRADJENTA if you:**

- are allergic to linagliptin or any of the ingredients in TRADJENTA. See the end of this Medication Guide for a complete list of ingredients in TRADJENTA.

Symptoms of a serious allergic reaction to TRADJENTA may include:

- skin rash, itching, flaking or peeling
- raised red patches on your skin (hives)
- swelling of your face, lips, tongue and throat that may cause difficulty in breathing or swallowing
- difficulty with swallowing or breathing

If you have any of these symptoms, stop taking TRADJENTA and call your doctor right away or go to the nearest hospital emergency room.

**What should I tell my doctor before taking TRADJENTA?**

**Before taking TRADJENTA, tell your doctor about all of your medical conditions, including if you:**

- have or have had inflammation of your pancreas (pancreatitis).
- are pregnant or plan to become pregnant. It is not known if TRADJENTA will harm your unborn baby. If you are pregnant, talk with your doctor about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if TRADJENTA passes into your breast milk. Talk with your doctor about the best way to feed your baby if you take TRADJENTA.

**Tell your doctor about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements.

TRADJENTA may affect the way other medicines work, and other medicines may affect how TRADJENTA works.

**Especially tell your doctor if you take:**

- insulin or other medicines that can lower your blood sugar
- rifampin (Rifadin, Rimactane, Rifater, Rifamate), an antibiotic that is used to treat tuberculosis

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

### How should I take TRADJENTA?

- Take TRADJENTA exactly as your doctor tells you to take it.
- Take 1 tablet 1 time each day with or without food.
- If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose and go back to your regular schedule. Do not take two doses of TRADJENTA at the same time.
- Your doctor may tell you to take TRADJENTA along with other diabetes medicines. Low blood sugar can happen more often when TRADJENTA is taken with certain other diabetes medicines. See “**What are the possible side effects of TRADJENTA?**”
- If you take too much TRADJENTA, call your doctor or local poison control center or go to the nearest hospital emergency room right away.
- Check your blood sugar as your doctor tells you to.

### What are the possible side effects of TRADJENTA?

#### TRADJENTA may cause serious side effects, including:

- See “**What is the most important information I should know about TRADJENTA?**”
- **Low blood sugar (hypoglycemia).** If you take TRADJENTA with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take TRADJENTA. Signs and symptoms of low blood sugar may include:
  - headache    ○ drowsiness    ○ weakness    ○ dizziness    ○ confusion
  - irritability    ○ hunger    ○ fast heartbeat    ○ sweating    ○ shaking or feeling jittery
- **Allergic (hypersensitivity) reactions.** Serious allergic reactions have happened in people who are taking TRADJENTA. Symptoms may include:
  - swelling of your face, lips, throat, and other areas on your skin    ○ difficulty with swallowing or breathing
  - raised, red areas on your skin (hives)    ○ skin rash, itching, flaking, or peelingIf you have any of these symptoms, stop taking TRADJENTA and call your doctor right away or go to the nearest hospital emergency room.
- **Joint pain.** Some people who take medicines called DPP-4 inhibitors like TRADJENTA, may develop joint pain that can be severe. Call your doctor if you have severe joint pain.
- **Skin reaction.** Some people who take medicines called DPP-4 inhibitors like TRADJENTA, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your doctor right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your doctor may tell you to stop taking TRADJENTA.

**The most common side effects of TRADJENTA include** stuffy or runny nose and sore throat, cough, **and** diarrhea.

Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of TRADJENTA. For more information, ask your doctor or pharmacist.

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 TRADJENTA?

- Store TRADJENTA at room temperature between 68°F and 77°F (20°C and 25°C).

#### Keep TRADJENTA and all medicines out of the reach of children.

### General information about the safe and effective use of TRADJENTA.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use TRADJENTA for a condition for which it was not prescribed. Do not give TRADJENTA to other people, even if they have the same symptoms you have. It may harm them.

You can ask your pharmacist or doctor for information about TRADJENTA that is written for health professionals.

### What are the ingredients in TRADJENTA?

**Active Ingredient:** linagliptin

**Inactive Ingredients:** mannitol, pregelatinized starch, corn starch, copovidone, and magnesium stearate. The film coating contains the following inactive ingredients: hypromellose, titanium dioxide, talc, polyethylene glycol, and red ferric oxide.

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For more information about TRADJENTA, including current prescribing information and Medication Guide, go to [www.TRADJENTA.com](http://www.TRADJENTA.com), or scan the code below, or call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257, or (TTY) 1-800-459-9906.

