

MEDICATION GUIDE
JENTADUETO® XR (JEN ta doo e toe XR)
(linagliptin and metformin hydrochloride extended-release tablets)
for oral use

Read this Medication Guide carefully before you start taking JENTADUETO XR 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 JENTADUETO XR, ask your doctor or pharmacist.

What is the most important information I should know about JENTADUETO XR?

JENTADUETO XR can cause serious side effects, including:

1. Lactic acidosis. Metformin hydrochloride, one of the medicines in JENTADUETO XR, can cause a rare but serious condition called lactic acidosis (a build-up of lactic acid in the blood) that can cause death. Lactic acidosis is a medical emergency and must be treated in a hospital.

Stop taking JENTADUETO XR and call your doctor right away or go to the nearest hospital emergency room if you get any of the following symptoms of lactic acidosis:

- feel very weak and tired
- have unusual (not normal) muscle pain
- have trouble breathing
- have unexplained stomach or intestinal problems with nausea and vomiting, or diarrhea
- have unusual sleepiness or sleep longer than usual
- feel cold, especially in your arms and legs
- feel dizzy or lightheaded
- have a slow or irregular heartbeat

You have a higher chance of getting lactic acidosis with JENTADUETO XR if you:

- have severe kidney problems.
- have liver problems.
- drink a lot of alcohol (very often or short-term "binge" drinking).
- get dehydrated (lose a large amount of body fluids). This can happen if you are sick with a fever, vomiting, or diarrhea. Dehydration can also happen when you sweat a lot with activity or exercise and do not drink enough fluids.
- have certain x-ray tests with injectable dyes or contrast agents.
- have surgery or other procedures for which you need to restrict the amount of food and liquid you eat and drink.
- have congestive heart failure.
- have a heart attack, severe infection, or stroke.
- are 65 years of age or older.

Tell your doctor if you have any of the problems in the list above. Tell your doctor that you are taking JENTADUETO before you have surgery or x-ray tests. Your doctor may decide to stop your JENTADUETO XR for a while if you have surgery or certain x-ray tests. JENTADUETO XR can have other serious side effects. See **"What are the possible side effects of JENTADUETO XR?"**

2. 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 JENTADUETO XR, tell your doctor if you have ever had:

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

Stop taking JENTADUETO XR 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.

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

Before you start taking JENTADUETO XR, 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 JENTADUETO XR?

- JENTADUETO XR is a prescription medicine that contains 2 diabetes medicines, linagliptin (TRADJENTA) and metformin hydrochloride. JENTADUETO XR can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes.
- JENTADUETO XR is not for people with type 1 diabetes.
- JENTADUETO XR 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 JENTADUETO XR.
- It is not known if JENTADUETO XR is safe and effective in children under 18 years of age.

Who should not take JENTADUETO XR?

Do not take JENTADUETO XR if you:

- have severe kidney problems.
- have a condition called metabolic acidosis or diabetic ketoacidosis (increased ketones in the blood or urine).
- are allergic to linagliptin (TRADJENTA), metformin, or any of the ingredients in JENTADUETO XR. See the end of this Medication Guide for a complete list of ingredients in JENTADUETO XR.

Symptoms of a serious allergic reaction to JENTADUETO XR 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 JENTADUETO XR and call your doctor right away or go to the nearest hospital emergency room.

What should I tell my doctor before taking JENTADUETO XR?

Before taking JENTADUETO XR, tell your doctor about all of your medical conditions, including if you:

- have or have had inflammation of your pancreas (pancreatitis).
- have kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- are 65 years of age or older.
- drink alcohol very often, or drink a lot of alcohol in short term ("binge" drinking).
- are going to get an injection of dye or contrast agents for an x-ray procedure. JENTADUETO XR may need to be stopped for a short time. Talk to your doctor about when you should stop JENTADUETO XR and when you should start JENTADUETO XR again. See "**What is the most important information I should know about JENTADUETO XR?**"
- have type 1 diabetes. JENTADUETO XR should not be used to treat people with type 1 diabetes.
- have low levels of vitamin B₁₂ in your blood.
- are pregnant or plan to become pregnant. It is not known if JENTADUETO XR 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. JENTADUETO XR may pass into your breast milk and may harm your baby. Talk with your doctor about the best way to feed your baby if you take JENTADUETO XR.
- are a woman who has not gone through menopause (premenopausal) who does not have periods regularly or at all. JENTADUETO XR can cause the release of an egg from an ovary in a woman (ovulation). This can increase your chance of getting pregnant. Tell your doctor right away if you become pregnant while taking JENTADUETO XR.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. JENTADUETO XR may affect the way other medicines work, and other medicines may affect how JENTADUETO XR works.

Especially tell your doctor if you take:

- insulin or other medicines that can lower your blood sugar
- diuretics (water pills)
- 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 JENTADUETO XR?

- Take JENTADUETO XR exactly as your doctor tells you to take it.
- Take JENTADUETO XR 1 time each day with a meal. Taking JENTADUETO XR with a meal may lower your chance of having an upset stomach.

- Swallow JENTADUETO XR tablets whole. Do not break, cut, crush, dissolve, or chew JENTADUETO XR tablets. If you cannot swallow JENTADUETO XR tablets whole, tell your doctor.
- You may see something that looks like the JENTADUETO XR tablet in your stool (bowel movement). If you see tablets in your stool, talk to your doctor. Do not stop taking JENTADUETO XR without talking to your doctor.
- If you miss a dose, take it with food 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 2 doses of JENTADUETO XR at the same time.
- If you take too much JENTADUETO XR, call your doctor or local poison control center or go to the nearest hospital emergency room right away.
- Your doctor may tell you to take JENTADUETO XR along with other diabetes medicines. Low blood sugar can happen more often when JENTADUETO XR is taken with certain other diabetes medicines. See "**What are the possible side effects of JENTADUETO XR?**"
- Check your blood sugar as your doctor tells you to.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with JENTADUETO XR.

What should I avoid while taking JENTADUETO XR?

Avoid drinking alcohol very often or drinking a lot of alcohol in a short period of time ("binge" drinking). It can increase your chances of getting serious side effects.

What are the possible side effects of JENTADUETO XR?

JENTADUETO XR may cause serious side effects, including:

- See "**What is the most important information I should know about JENTADUETO XR?**"
- **Low blood sugar (hypoglycemia).** If you take JENTADUETO XR with another medicine that can cause low blood sugar, such as 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 JENTADUETO XR. Signs and symptoms of low blood sugar may include:
 - headache
 - irritability
 - drowsiness
 - hunger
 - weakness
 - fast heartbeat
 - dizziness
 - sweating
 - confusion
 - shaking or feeling jittery
- **Allergic (hypersensitivity) reactions.** Serious allergic reactions have happened in people who are taking JENTADUETO XR. 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 peeling
 If you have any of these symptoms, stop taking JENTADUETO XR and call your doctor right away or go to the nearest hospital emergency room.
- **Low vitamin B₁₂ (vitamin B₁₂ deficiency).** Using metformin for long periods of time may cause a decrease in the amount of vitamin B₁₂ in your blood, especially if you have had low vitamin B₁₂ blood levels before. Your doctor may do blood tests to check your vitamin B₁₂ levels.
- **Joint pain.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in JENTADUETO XR, 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, one of the medicines in JENTADUETO XR, 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 JENTADUETO XR.

The most common side effects of JENTADUETO XR include stuffy or runny nose and sore throat **and** diarrhea. Tell your doctor if you have any side effects that bother you or that do not go away.

These are not all the possible side effects of JENTADUETO XR. 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 JENTADUETO XR?

- Store JENTADUETO XR at room temperature between 68°F and 77°F (20°C and 25°C).
- Keep tablets dry.

Keep JENTADUETO XR and all medicines out of the reach of children.

General information about the safe and effective use of JENTADUETO XR.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use JENTADUETO XR for a condition for which it was not prescribed. Do not give JENTADUETO XR 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 JENTADUETO XR that is written for health professionals.

What are the ingredients in JENTADUETO XR?

Active Ingredients: linagliptin and metformin hydrochloride

Inactive Ingredients: polyethylene oxide, hypromellose, and magnesium stearate. The coating contains the following inactive ingredients: hydroxypropyl cellulose, hypromellose, talc, titanium dioxide, arginine, polyethylene glycol, ferric oxide yellow (2.5 mg/1000 mg), carnauba wax, ferrousferrous oxide, propylene glycol, and isopropyl alcohol.

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



This Medication Guide has been approved by the U.S. Food and Drug Administration

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