

MEDICATION GUIDE
JENTADUETO® XR (JEN ta doo e' toe XR)
(linagliptin and metformin hydrochloride extended-release)
Tablets

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?

Serious side effects can happen in people taking JENTADUETO XR, including:

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

Call your doctor right away if you have any of the following symptoms, which could be signs of lactic acidosis:

- you feel cold in your hands or feet
- you feel dizzy or lightheaded
- you have a slow or irregular heart beat
- you feel very weak or tired
- you have unusual (not normal) muscle pain
- you have trouble breathing
- you feel sleepy or drowsy
- you have stomach pains, nausea or vomiting

Most people who have had lactic acidosis with metformin have other things that, combined with metformin, led to the lactic acidosis. Tell your doctor if you have any of the following, because you have a higher chance of getting lactic acidosis with JENTADUETO XR if you:

- have severe kidney problems or your kidneys are affected by certain x-ray tests that use injectable dye.
- have liver problems
- drink alcohol very often, or drink a lot of alcohol in 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 surgery
- have a heart attack, severe infection, or stroke

The best way to keep from having a problem with lactic acidosis from metformin is to tell your doctor if you have any of the problems in the list above. Your doctor may decide to stop your JENTADUETO XR for a while if you have any of these things. 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)
- stones in your gallbladder (gallstones)
- a history of alcoholism
- 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 through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

3.Heart failure. Heart failure means that 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 and metformin. JENTADUETO XR can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes when treatment with both linagliptin and metformin is appropriate.
- 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, 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 contact your doctor or go to the nearest hospital emergency room right away.

What should I tell my doctor before using JENTADUETO XR?

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

- have or have had inflammation of your pancreas (pancreatitis).
- have severe kidney problems
- have liver problems
- have heart problems, including congestive heart failure
- 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 any other medical conditions
- 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 a premenopausal woman (before the "change of life"), who does not have periods regularly or at all.** Talk to your doctor about birth control choices while taking JENTADUETO XR if you are not planning to become pregnant since JENTADUETO XR may increase your chance of becoming pregnant. Tell your doctor right away if you become pregnant while taking JENTADUETO XR.
- are breastfeeding or plan to breastfeed. It is not known if JENTADUETO XR passes into your breast milk. Talk with your doctor about the best way to feed your baby if you take 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:

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

Ask your doctor or pharmacist for a list of these medicines if you are not sure if your medicine is one that is listed above. Know the medicines you take. Keep a list of them and show it to 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 each day with a meal. Taking JENTADUETO XR with a meal may lower your chance of having an upset stomach.
- Take JENTADUETO XR 1 time each day.
- Take JENTADUETO XR tablets whole. Do not break, cut, crush, dissolve, or chew JENTADUETO XR tablets before swallowing. 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 Poison Control Center at 1-800-222-1222 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?**"
- You may need to stop taking JENTADUETO XR for a short time. Call your doctor for instructions if you:
 - are dehydrated (have lost too much body fluid). Dehydration can occur if you are sick with severe vomiting, diarrhea, or fever, or if you drink a lot less fluid than normal.
 - plan to have surgery
 - are going to get an injection of dye or contrast agent for an x-ray procedure. See "**What is the most important information I should know about JENTADUETO XR?**" and "**Who should not take JENTADUETO XR?**"
- When your body is under some types of stress, such as fever, trauma (such as a car accident), infection, or surgery, the amount of diabetes medicine that you need may change. Tell your doctor right away if you have any of these conditions and follow your doctor's instructions.
- Check your blood sugar as your doctor tells you to.
- Stay on your prescribed diet and exercise program while taking JENTADUETO XR.
- Your doctor will check your diabetes with regular blood tests, including your blood sugar levels and your hemoglobin A1C.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with JENTADUETO XR.

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 medication 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 heart beat
 - dizziness
 - sweating
 - confusion
 - feeling jittery
- **Allergic (hypersensitivity) reactions.** Serious allergic reactions can happen after your first dose or up to 3 months after starting 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 peelingIf you have these symptoms, stop taking JENTADUETO XR and call your doctor or go to the nearest hospital emergency room right away.
- **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.

These are not all the possible side effects of JENTADUETO XR. For more information, ask your doctor or pharmacist. Tell your doctor if you have any side effects that bother you or that do not go away.

- 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 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 Medication Guides. 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.

This Medication Guide summarizes the most important information about JENTADUETO XR. If you would like more information, talk with your doctor. 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, ferrous ferric oxide, propylene glycol, and isopropyl alcohol.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and/or the insulin that your body produces does not work as well as it should. Your body can also make too much sugar. When this happens, sugar (glucose) builds up in the blood. This can lead to serious medical problems.

The main goal of treating diabetes is to lower your blood sugar to a normal level. High blood sugar can be lowered by diet and exercise, and by certain medicines when necessary.

Talk to your doctor about how to prevent, recognize, and take care of low blood sugar (hypoglycemia), high blood sugar (hyperglycemia), and other problems you have because of your diabetes.

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