

**MEDICATION GUIDE**  
**TRIJARDY® XR (try-JAR-dee XR)**  
**(empagliflozin, linagliptin, and metformin hydrochloride extended-release tablets)**  
**for oral use**

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

TRIJARDY XR can cause serious side effects, including:

- 1. Lactic Acidosis. Metformin hydrochloride (HCl), one of the medicines in TRIJARDY 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 TRIJARDY XR and call your healthcare provider 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 TRIJARDY XR if you:**

- have moderate to 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 procedure 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 healthcare provider if you have any of the problems in the list above. Tell your healthcare provider that you are taking TRIJARDY XR before you have surgery or x-ray tests. Your healthcare provider may need to stop your TRIJARDY XR for a while if you have surgery or certain x-ray tests. TRIJARDY XR can have other serious side effects. See **“What are the possible side effects of TRIJARDY XR?”**

- 2. Diabetic ketoacidosis (increased ketones in your blood or urine) in people with type 1 and other ketoacidosis.**

TRIJARDY XR can cause ketoacidosis that can be life-threatening and may lead to death. Ketoacidosis is a serious condition which needs to be treated in a hospital. People with type 1 diabetes have a high risk of getting ketoacidosis. People with type 2 diabetes or pancreas problems also have an increased risk of getting ketoacidosis. Ketoacidosis can also happen in people who: are sick, cannot eat or drink as usual, skip meals, are on a diet high in fat and low in carbohydrates (ketogenic diet), take less than the usual amount of insulin or miss insulin doses, drink too much alcohol, have a loss of too much fluid from the body (volume depletion), or who have surgery. Ketoacidosis can happen even if your blood sugar is less than 250 mg/dL. Your healthcare provider may ask you to periodically check ketones in your urine or blood.

**Stop taking TRIJARDY XR and call your healthcare provider or get medical help right away if you get any of the following. If possible, check for ketones in your urine or blood, even if your blood sugar is less than 250 mg/dL:**

- nausea
- vomiting
- stomach-area (abdominal) pain
- tiredness
- trouble breathing
- ketones in your urine or blood

- 3. 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 TRIJARDY XR, tell your healthcare provider 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 TRIJARDY XR and call your healthcare provider 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.

**4. Dehydration. TRIJARDY XR can cause some people to become dehydrated (the loss of body water and salt). Dehydration may cause you to feel dizzy, faint, light-headed, or weak, especially when you stand up (orthostatic hypotension). There have been reports of sudden worsening of kidney function in people who are taking TRIJARDY XR.** You may be at higher risk of dehydration if you:

- take medicines to lower your blood pressure, including diuretics (water pills)
- are on a low sodium (salt) diet
- have kidney problems
- are 65 years of age or older

Talk to your healthcare provider about what you can do to prevent dehydration including how much fluid you should drink on a daily basis. Call your healthcare provider right away if you reduce the amount of food or liquid you drink, for example if you are sick or you cannot eat, or start to lose liquids from your body, for example from vomiting, diarrhea or being in the sun too long.

**5. Vaginal yeast infection.** Symptoms of a vaginal yeast infection include:

- vaginal odor
- white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese)
- vaginal itching

**6. Yeast infection of the skin around the penis (balanitis or balanoposthitis).** Swelling of an uncircumcised penis may develop that makes it difficult to pull back the skin around the tip of the penis. Other symptoms of a yeast infection of the penis include:

- redness, itching, or swelling of the penis
- rash of the penis
- foul smelling discharge from the penis
- pain in the skin around the penis

Talk to your healthcare provider about what to do if you get symptoms of a yeast infection of the vagina or penis. Your healthcare provider may suggest you use an over-the-counter antifungal medicine. Talk to your healthcare provider right away if you use an over-the-counter antifungal medication and your symptoms do not go away.

#### **What is TRIJARDY XR?**

TRIJARDY XR is a prescription medicine that contains 3 diabetes medicines, empagliflozin (JARDIANCE), linagliptin (TRADJENTA), and metformin HCl. TRIJARDY XR can be used:

- along with diet and exercise to lower blood sugar (glucose) in adults with type 2 diabetes,
- in adults with type 2 diabetes who have known cardiovascular disease when empagliflozin (JARDIANCE), one of the medicines in TRIJARDY XR, is needed to reduce the risk of cardiovascular death.
- TRIJARDY XR is not for use to lower blood sugar (glucose) in people with type 1 diabetes. It may increase their risk of diabetic ketoacidosis (increased ketones in 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 TRIJARDY XR.
- It is not known if TRIJARDY XR is safe and effective in children.

#### **Who should not take TRIJARDY XR?**

**Do not take TRIJARDY XR if you:**

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

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

#### **What should I tell my healthcare provider before taking TRIJARDY XR?**

**Before taking TRIJARDY XR, tell your healthcare provider about all of your medical conditions, including if you:**

- have type 1 diabetes or have had diabetic ketoacidosis.
- have a decrease in your insulin dose.
- have a serious infection.
- have a history of infection of the vagina or penis.
- have a history of amputation.

- have kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- are 65 years of age or older.
- have a history of urinary tract infections or problems with urination.
- are on a low sodium (salt) diet. Your healthcare provider may change your diet or your dose.
- are going to have surgery. Your healthcare provider may stop your TRIJARDY XR before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking TRIJARDY XR and when to start it again.
- are eating less, or there is a change in your diet.
- are dehydrated.
- have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas.
- drink alcohol very often or drink a lot of alcohol in the short term (“binge” drinking).
- have ever had an allergic reaction to TRIJARDY XR.
- are going to get an injection of dye or contrast agents for an x-ray procedure. TRIJARDY XR may need to be stopped for a short time. Talk to your healthcare provider about when you should stop TRIJARDY XR and when you should start TRIJARDY XR again. See **“What is the most important information I should know about TRIJARDY XR?”**
- have low levels of vitamin B<sub>12</sub> in your blood.
- are pregnant or plan to become pregnant. TRIJARDY XR may harm your unborn baby. If you become pregnant while taking TRIJARDY XR, tell your healthcare provider as soon as possible. Talk with your healthcare provider about the best way to control your blood sugar while you are pregnant.
- are breastfeeding or plan to breastfeed. TRIJARDY XR may pass into your breast milk and may harm your baby. Talk with your healthcare provider about the best way to feed your baby if you are taking TRIJARDY XR. Do not breastfeed while taking TRIJARDY XR.
- are a person who has not gone through menopause (premenopausal) who does not have periods regularly or at all. TRIJARDY XR can cause the release of an egg from an ovary in a person (ovulation). This can increase your chance of getting pregnant. Tell your healthcare provider right away if you become pregnant while taking TRIJARDY XR.

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

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

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 take TRIJARDY XR?**

- Take TRIJARDY XR exactly as your healthcare provider tells you to take it.
- Take TRIJARDY XR by mouth 1 time each day with a meal in the morning. Taking TRIJARDY XR with a meal may lower your chance of having an upset stomach.
- Swallow TRIJARDY XR tablets whole. Do not break, cut, crush, dissolve, or chew TRIJARDY XR. If you cannot swallow TRIJARDY XR tablets whole, tell your healthcare provider.
- You may see something that looks like the TRIJARDY XR tablet in your stool (bowel movement). This is not harmful and should not affect the way TRIJARDY XR works to control your diabetes.
- Your healthcare provider will tell you how much TRIJARDY XR to take and when to take it. Your healthcare provider may change your dose if needed.
- Your healthcare provider may tell you to take TRIJARDY XR along with other diabetes medicines. Low blood sugar can happen more often when TRIJARDY XR is taken with certain other diabetes medicines. See **“What are the possible side effects of TRIJARDY XR?”**
- If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take two doses of TRIJARDY XR at the same time. Talk with your healthcare provider if you have questions about a missed dose.
- If you take too much TRIJARDY XR, call your healthcare provider or Poison Help line at 1-800-222-1222, or go to the nearest hospital emergency room right away.
- When taking TRIJARDY XR, you may have sugar in your urine, which will show up on a urine test.
- 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 you need may change. Tell your healthcare provider right away if you have any of these conditions and follow your healthcare provider’s instructions.
- Your healthcare provider may do certain blood tests before you start TRIJARDY XR and during treatment as needed.

### What should I avoid while taking TRIJARDY 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 TRIJARDY XR?

TRIJARDY XR may cause serious side effects, including:

- See “What is the most important information I should know about TRIJARDY XR?”
- **Serious urinary tract infections.** Serious urinary tract infections that may lead to hospitalization have happened in people who are taking empagliflozin, one of the medicines in TRIJARDY XR. Tell your healthcare provider if you have any signs or symptoms of a urinary tract infection such as a burning feeling when passing urine, a need to urinate often, the need to urinate right away, pain in the lower part of your stomach (pelvis), or blood in the urine. Sometimes people also may have a fever, back pain, nausea or vomiting.
- **Low blood sugar (hypoglycemia).** If you take TRIJARDY XR 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 TRIJARDY XR. Signs and symptoms of low blood sugar may include:
  - headache
  - irritability
  - confusion
  - dizziness
  - drowsiness
  - hunger
  - shaking or feeling jittery
  - sweating
  - weakness
  - fast heartbeat
- **A rare but serious bacterial infection that causes damage to the tissue under the skin (necrotizing fasciitis) in the area between and around the anus and genitals (perineum).** Necrotizing fasciitis of the perineum has happened in people who take empagliflozin, one of the medicines in TRIJARDY XR. Necrotizing fasciitis of the perineum may lead to hospitalization, may require multiple surgeries, and may lead to death. **Seek medical attention immediately if you have a fever or you are feeling very weak, tired or uncomfortable (malaise), and you develop any of the following symptoms in the area between and around your anus and genitals:**
  - pain or tenderness
  - swelling
  - redness of skin (erythema)
- **Amputations. SGLT2 inhibitors may increase your risk of lower limb amputations.**

You may be at a higher risk of lower limb amputation if you:

- have a history of amputation
- have had blocked or narrowed blood vessels, usually in your leg
- have had diabetic foot infection, ulcers or sores

**Call your healthcare provider right away if you have new pain or tenderness, any sores, ulcers, or infections in your leg or foot.** Talk to your healthcare provider about proper foot care.

- **Serious allergic reactions.** If you have any symptoms of a serious allergic reaction, stop taking TRIJARDY XR and call your healthcare provider right away or go to the nearest hospital emergency room. See “Who should not take TRIJARDY XR?”.
- **Low vitamin B<sub>12</sub> (vitamin B<sub>12</sub> deficiency).** Using metformin for long periods of time may cause a decrease in the amount of vitamin B<sub>12</sub> in your blood, especially if you have had low vitamin B<sub>12</sub> blood levels before. Your healthcare provider may do blood tests to check your vitamin B<sub>12</sub> levels.
- **Joint pain.** Some people who take linagliptin, one of the medicines in TRIJARDY XR, may develop joint pain that can be severe. Call your healthcare provider if you have severe joint pain.
- **Skin reaction.** Some people who take medicines called DPP-4 inhibitors, one of the medicines in TRIJARDY XR, may develop a skin reaction called bullous pemphigoid that can require treatment in a hospital. Tell your healthcare provider right away if you develop blisters or the breakdown of the outer layer of your skin (erosion). Your healthcare provider may tell you to stop taking TRIJARDY XR.
- **Heart failure.** Heart failure means your heart does not pump blood well enough.

**Before you start taking TRIJARDY XR,** tell your healthcare provider if you have ever had heart failure or have problems with your kidneys. Contact your healthcare provider 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.

**The most common side effects of TRIJARDY XR include:**

- upper respiratory tract infection
- constipation
- urinary tract infection
- headache

- stuffy or runny nose and sore throat
- diarrhea
- inflammation of the stomach and intestine (gastroenteritis)

Tell 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 TRIJARDY XR. For more information, ask your healthcare provider 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 TRIJARDY XR?

- Store TRIJARDY XR at room temperature between 68°F to 77°F (20°C to 25°C).
- Keep TRIJARDY XR tablets dry.
- **Keep TRIJARDY XR and all medicines out of the reach of children.**

#### General information about the safe and effective use of TRIJARDY XR.

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

You can ask your pharmacist or healthcare provider for information about TRIJARDY XR that is written for health professionals.

#### What are the ingredients in TRIJARDY XR?

**Active ingredients:** empagliflozin, linagliptin, and metformin hydrochloride

**Inactive ingredients:** Tablet core contains: hypromellose, magnesium stearate, and polyethylene oxide. The Film Coatings and Printing Ink contain: ammonium hydroxide, arginine, carnauba wax, ferric oxide yellow and ferric oxide red (10 mg/5 mg/1,000 mg), ferrousferrous oxide and ferric oxide red (12.5 mg/2.5 mg/1,000 mg), ferrousferrous oxide and ferric oxide yellow (5 mg/2.5 mg/1,000 mg and 25 mg/5 mg/1,000 mg), hydroxypropyl cellulose, hypromellose, isopropyl alcohol, n-butyl alcohol, polyethylene glycol, propylene glycol, purified water, shellac glaze, talc, and titanium dioxide.

Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA

Marketed by: Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT 06877 USA and Eli Lilly and Company, Indianapolis, IN 46285 USA

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COL9014DK032023

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



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

Revised: October 2023