

For adults with type 2 diabetes, to lower blood sugar, in addition to diet & exercise

Trijardy[®] XR

(empagliflozin/linagliptin/metformin HCl
extended-release tablets)

25mg/5mg/1000mg, 12.5mg/2.5mg/1000mg,
10mg/5mg/1000mg, 5mg/2.5mg/1000mg

Your Guide to Getting Started

3-in-1 TRIJARDY XR may help
lower your A1C



WHAT IS TRIJARDY XR?

TRIJARDY XR is a prescription medicine that contains 3 diabetes medicines, empagliflozin (JARDIANCE), linagliptin (TRADJENTA), and metformin hydrochloride. **TRIJARDY XR** can be used along with diet and exercise to lower blood sugar in adults with type 2 diabetes, and 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 people with type 1 diabetes. It may increase their risk of diabetic ketoacidosis (increased ketones in the blood or urine).

If you have had pancreatitis (inflammation of the pancreas) in the past, it is not known if you have a higher chance of getting pancreatitis while you take **TRIJARDY XR**.

Please see full Important Safety Information for TRIJARDY XR on pages 8-10, and [Prescribing Information](#) and [Medication Guide](#).

Find out if you're eligible for savings and get support now!

For adults with type 2 diabetes, to lower blood sugar, in addition to diet & exercise

IMAGINE A NEW LOW IN YOUR A1C

You've got a lot on your plate when it comes to self-managing your type 2 diabetes, so it's normal to feel overwhelmed from time to time. That's why it's important to stay motivated and have a plan. It starts with a healthy diet and exercise, and adding TRIJARDY XR to help lower your A1C.

Aiming lower is the name of the game, so here are a few things to remember:

A healthy diet

Diet has a big impact on your blood sugar and helps manage your weight. Consider trying portion control and keeping an eye on ingredients to help with caloric intake.



Staying active

Just like a healthy diet, exercise is an important part of your daily routine. Whether it's walking, swimming, or taking the stairs, it all makes a difference.

Owning your routine

It's up to you to partner with your doctor to create a routine, from diet to exercise to taking a medication that's right for helping you.



Get helpful tips to help manage your diabetes and lower your A1C

[LEARN MORE >](#)

IMPORTANT SAFETY INFORMATION

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

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

Stop taking TRIJARDY 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 muscle pain, have trouble breathing, have stomach or intestinal problems with nausea and vomiting, or diarrhea, feel sleepy or sleep longer than usual, feel cold in your arms and legs, feel dizzy or lightheaded, or have a slow or irregular heartbeat.

Trijardy XR
(empagliflozin/linagliptin/metformin HCl
extended-release tablets)

25mg/5mg/1000mg, 12.5mg/2.5mg/1000mg,
10mg/5mg/1000mg, 5mg/2.5mg/1000mg

GET TO KNOW TRIJARDY XR

**TRIJARDY XR is formulated
with 3 medications that help lower A1C**



With TRIJARDY XR, you get the possibility of convenient control

Three medications in a once-daily pill that help lower A1C, TRIJARDY XR can easily fit into a morning routine.

How does TRIJARDY XR work?

TRIJARDY XR combines JARDIANCE (empagliflozin), TRADJENTA (linagliptin), and metformin hydrochloride—which work together to lower A1C, along with diet and exercise. And in adults with type 2 diabetes who also have known heart disease, JARDIANCE, one of the medicines in TRIJARDY XR, can reduce the risk of cardiovascular death.

IMPORTANT SAFETY INFORMATION (cont'd)

You have a higher chance of getting lactic acidosis with TRIJARDY XR if you: have moderate to severe kidney problems; have liver problems; drink alcohol (very often or short term "binge" drinking); get dehydrated (lose a large amount of body fluids); have x-ray tests that use injectable dye; have surgery; have congestive heart failure; have a heart attack, severe infection, or stroke, or are 65 years of age or older.

Inflammation of the pancreas (pancreatitis) is another serious side effect that can happen to people taking TRIJARDY XR. Pancreatitis may be severe and lead to death. **Before you start taking TRIJARDY XR** tell your doctor if you have ever had pancreatitis, a history of alcoholism, gallstones, or high triglyceride levels.

Please see full Important Safety Information for TRIJARDY XR on pages 8-10, and [Prescribing Information](#) and [Medication Guide](#).

TAKING TRIJARDY XR

TRIJARDY XR is a 3-in-1 medication that, along with diet and exercise, helps lower A1C. It's taken once daily in the morning with food.

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TRIJARDY XR has 4 different dosing options

That means your doctor can customize your treatment with TRIJARDY XR to fit your needs.

The pill is similar in size to the Metformin XR you may already be taking.



TRIJARDY XR
5 mg/2.5 mg/1000 mg
20 mm tablet



Metformin XR (Glumetza)
1000 mg
20 mm tablet

Note: This is representative of the comparison between pill size. Pills displayed are not actual size.

Always take TRIJARDY XR exactly as prescribed

Tell your doctor 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.

Keep reading to learn about results with TRIJARDY XR.

IMPORTANT SAFETY INFORMATION (cont'd)

Stop taking **TRIJARDY 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.

Ketoacidosis (increased ketones in your blood or urine). Ketoacidosis is a serious condition which needs to be treated in the hospital. Ketoacidosis may lead to death. Ketoacidosis occurs in people with type 1 diabetes and can also occur in people with type 2 diabetes taking **TRIJARDY XR, even if blood sugar is less than 250 mg/dL.** Ketoacidosis has also happened in people with diabetes who were sick or who had surgery during treatment with **TRIJARDY XR.**

RESULTS WITH TRIJARDY XR



How TRIJARDY XR performed in a clinical trial

58% of people with a baseline A1C above 7% (n=74) achieved an A1C of less than 7.0.*



ADA-approved target

The A1C target suggested by the American Diabetes Association (ADA) is less than 7.0%. You and your doctor will determine your personal A1C goals together.



Your A1C numbers will help you track your progress

A1C is an average of your blood sugar over 2 to 3 months, and will help you measure how your type 2 diabetes treatment is going while you take TRIJARDY XR.

*In a 6-month study, 686 patients who were taking metformin with an A1C above 7% were given empagliflozin 10 mg along with linagliptin 5 mg or empagliflozin 25 mg along with linagliptin 5 mg. This resulted in 58% of patients taking metformin, empagliflozin 10 mg, and linagliptin 5 mg achieving an A1C below 7%, and 62% of patients taking metformin, empagliflozin 25 mg, and linagliptin 5 mg achieving an A1C below 7%. When they added empagliflozin 10 mg or 25 mg alone, 28% and 33% of patients achieved an A1C below 7%. When linagliptin 5 mg alone was added, 36% of patients achieved an A1C below 7%.

Wait, there's more!

While not indicated for weight loss, TRIJARDY XR could help you lower weight.

IMPORTANT SAFETY INFORMATION (cont'd)

Stop taking TRIJARDY XR and call your doctor right away or go to the nearest hospital emergency room if you get any of the following symptoms, and, if possible, check for ketones in your urine:

- nausea
- vomiting
- stomach-area (abdominal) pain
- tiredness
- trouble breathing

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. You may be at higher risk of dehydration if you have kidney problems, are 65 years of age or older, are on a low salt diet, or take medicines to lower your blood pressure, including water pills (diuretics). Talk to your doctor about what you can do to prevent dehydration.

Please see full Important Safety Information for TRIJARDY XR on pages 8-10, and [Prescribing Information](#) and [Medication Guide](#).

SIDE EFFECTS WITH TRIJARDY XR

Common side effects

The most common side effects experienced while taking TRIJARDY XR include upper respiratory tract infection, urinary tract infection, stuffy or runny nose and sore throat, diarrhea, constipation, headache, and inflammation of the stomach and intestine (gastroenteritis). These are not all the possible side effects of TRIJARDY XR. Tell your doctor if you have any side effect that bothers you or that does not go away.

Serious side effects

The serious side effects that may be experienced while taking TRIJARDY XR include lactic acidosis (a buildup of lactic acid in the blood), inflammation of the pancreas (pancreatitis), ketoacidosis (increased ketones in your blood and urine), dehydration, serious urinary tract infections, low blood sugar (hypoglycemia), necrotizing fasciitis, vaginal yeast infection, yeast infection of the penis, allergic reactions (hypersensitivity), vitamin B₁₂ deficiency, joint pain, skin reaction, and heart failure.



Keep your doctor informed about any noticeable changes you experience while taking a new medication. They may adjust your dose.

JOIN MY TRIJARDY XR SUPPORT

Find out if you're eligible for lower co-pay and sign up for more information

By simply joining, you'll receive valuable information and resources to support you on your journey with TRIJARDY XR. Plus, with a TRIJARDY XR Savings Card, your **co-pay could be as little as \$10*** a month for a 1- to 3-month prescription.

And you'll keep saving—as long as you qualify, you can continue using your card to save on TRIJARDY XR refills.*

Register for My TRIJARDY XR Support and savings!

Sign up

*TRIJARDY XR Savings Card Terms & Conditions apply



And don't forget to visit
TRIJARDYXR.com for tips and more

Please see full Important Safety Information for TRIJARDY XR on pages 8-10, and [Prescribing Information](#) and [Medication Guide](#).

IMPORTANT SAFETY INFORMATION (cont'd)

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 and urine)
- are allergic to empagliflozin, linagliptin, metformin, or any of the ingredients in **TRIJARDY XR**

TRIJARDY XR may cause serious side effects, including:

Serious urinary tract infections. Serious urinary tract infections can occur in people taking empagliflozin, one of the medicines in **TRIJARDY XR** and may lead to hospitalization. Tell your doctor if you have symptoms of a urinary tract infection, such as a burning feeling when passing urine, a need to urinate often or right away, pain in the lower part of your stomach or 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. Symptoms of low blood sugar may include headache, drowsiness, weakness, irritability, hunger, fast heartbeat, confusion, shaking or feeling jittery, dizziness, or sweating.

Necrotizing fasciitis. A rare but serious bacterial infection that causes damage to the tissue under the skin in the area between and around your anus and genitals (perineum). This bacterial infection has happened in women and men who take empagliflozin, one of the medications in **TRIJARDY XR**, and may lead to hospitalization, multiple surgeries, and death. **Seek medical attention immediately if you have fever or 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, and redness of skin (erythema).**

Vaginal yeast infection. Talk to your doctor if you have vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), and/or vaginal itching.

Yeast infection of the penis. Swelling of an uncircumcised penis may develop that makes it difficult to pull back the skin around the tip of the penis. Talk to your doctor if you have redness, itching or swelling of the penis, foul smelling discharge from the penis, rash of the penis or pain in the skin around the penis.

IMPORTANT SAFETY INFORMATION (cont'd)

Allergic (hypersensitivity) reactions. Symptoms of serious allergic reactions to **TRIJARDY XR** may include swelling of your face, lips, tongue, throat, and other areas of 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 **TRIJARDY 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 dipeptidyl peptidase-4 (DPP-4) inhibitors, one of the medicines in **TRIJARDY 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 **TRIJARDY XR**, may develop a skin reaction. Tell your doctor right away if you develop blisters.

Heart failure means your heart does not pump blood well enough. **Before you start taking TRIJARDY 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 or unusual tiredness. These may be symptoms of heart failure.

The most common side effects of TRIJARDY XR include upper respiratory tract infection, urinary tract infections, stuffy or runny nose and sore throat, diarrhea, constipation, headache, and inflammation of the stomach and intestine (gastroenteritis).

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

IMPORTANT SAFETY INFORMATION (cont'd)

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

- have kidney problems
- have liver problems
- have heart problems, including congestive heart failure
- are 65 years of age or older
- have a history of infection of the vagina or penis
- have a history of urinary tract infection or problems with urination
- are going to have surgery. Your doctor may stop your TRIJARDY XR before you have surgery. Talk to your doctor 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
- 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)
- 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 doctor about when you should stop TRIJARDY XR and when you should start it again

- have type 1 diabetes. TRIJARDY XR should not be used in people with type 1 diabetes
- have low levels of vitamin B₁₂ in your blood
- are pregnant or plan to become pregnant. TRIJARDY XR may harm your unborn baby. Tell your doctor right away if you become pregnant while taking TRIJARDY XR
- are breastfeeding or plan to breastfeed. TRIJARDY XR may pass into your breast milk and may harm your baby. 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. This can increase your chance of getting pregnant

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

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

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

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Please see [Prescribing Information](#) and [Medication Guide](#) for TRIJARDY XR.

Don't forget to visit TRIJARDYXR.com
for tips, support, and to find out if
you're eligible for savings!

Please see Medication Guide on pages 12-17.


Trijardy[®] XR
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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, 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 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 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 doctor if you have any of the problems in the list above. Tell your doctor that you are taking TRIJARDY XR before you have surgery or x-ray tests. Your doctor 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. 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 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 TRIJARDY 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. Ketoacidosis (increased ketones in your blood or urine). Ketoacidosis has happened in people who have **type 1 diabetes or type 2 diabetes**, during treatment with empagliflozin, one of the medicines in TRIJARDY XR. Ketoacidosis has also happened in people with diabetes who were sick or who had surgery during treatment with TRIJARDY XR. Ketoacidosis is a serious condition, which needs to be treated in a hospital. Ketoacidosis may lead to death. **Ketoacidosis can happen with TRIJARDY XR even if your blood sugar is less than 250 mg/dL. Stop taking TRIJARDY XR and call your doctor right away or go to the nearest hospital emergency room if you get any of the following symptoms:**

- nausea
- vomiting
- stomach-area (abdominal) pain
- tiredness
- trouble breathing

If you get any of these symptoms during treatment with TRIJARDY XR, if possible, check for ketones in your urine, even if your blood sugar is less than 250 mg/dL.

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:

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

Talk to your doctor about what you can do to prevent dehydration including how much fluid you should drink on a daily basis.

Talk to your doctor right away if you reduce the amount of food or liquid you drink, for example if you are sick or cannot eat, or start to lose liquids from your body, for example from vomiting, diarrhea or being in the sun too long.

What is TRIJARDY XR?

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

- along with diet and exercise to lower blood sugar 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 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 doctor right away or go to the nearest hospital emergency room.

What should I tell my doctor before taking TRIJARDY XR?

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

- have kidney problems.
- have liver problems.
- have heart problems, including congestive heart failure.
- are 65 years of age or older.
- have a history of infection of the vagina or penis.
- have a history of urinary tract infection or problems with urination.
- are going to have surgery. Your doctor may stop your TRIJARDY XR before you have surgery. Talk to your doctor 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.
- 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).
- 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 doctor 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 type 1 diabetes. TRIJARDY 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. TRIJARDY XR may harm your unborn baby. If you become pregnant while taking TRIJARDY XR, tell your doctor as soon as possible. Talk with your doctor 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 doctor 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 doctor right away if you become pregnant while taking TRIJARDY XR.

Tell your doctor 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.

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 TRIJARDY XR?

- Take TRIJARDY XR exactly as your doctor 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 doctor.
- 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.
- 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 TRIJARDY XR at the same time.
- Your doctor 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 take too much TRIJARDY XR, call your doctor or local poison control center or go to the nearest hospital emergency room right away.
- Your doctor will do blood tests to check how well your kidneys are working before and during your treatment with TRIJARDY XR.
- When taking TRIJARDY XR, you may have sugar in your urine, which will show up on a urine test.

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 doctor 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
- drowsiness
- weakness
- irritability
- hunger
- fast heartbeat
- confusion
- shaking or feeling jittery
- dizziness
- sweating

- **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 women and men 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)

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

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

- **Yeast infection of the penis (balanitis).** 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
- foul smelling discharge from the penis
- rash of the penis
- pain in the skin around the penis

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

- **Allergic (hypersensitivity) reactions.** Serious allergic reactions have happened in people who are taking TRIJARDY XR. Symptoms may include:

- swelling of your face, lips, tongue, 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 TRIJARDY 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 TRIJARDY 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 TRIJARDY 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 TRIJARDY XR.

- **Heart failure.** Heart failure means your heart does not pump blood well enough. **Before you start taking TRIJARDY 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.

The most common side effects of TRIJARDY XR include:

- upper respiratory tract infection
- urinary tract infection
- stuffy or runny nose and sore throat
- diarrhea
- constipation
- headache
- inflammation of the stomach and intestine (gastroenteritis)

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 TRIJARDY 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 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 doctor 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: polyethylene oxide, hypromellose, and magnesium stearate. The Film Coatings and Printing Ink contain: hydroxypropyl cellulose, hypromellose, talc, titanium dioxide, arginine, polyethylene glycol, carnauba wax, purified water, shellac glaze, n-butyl alcohol, propylene glycol, ammonium hydroxide, isopropyl alcohol, ferrousferic oxide and ferric oxide yellow (5 mg/2.5 mg/1000 mg and 25 mg/5 mg/1000 mg), ferric oxide yellow and ferric oxide red (10 mg/5 mg/1000 mg), and ferrousferic oxide and ferric oxide red (12.5 mg/2.5 mg/1000 mg).

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



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