

MEDICATION GUIDE
JARDIANCE® (jar DEE ans)
(empagliflozin tablets)
for oral use

What is the most important information I should know about JARDIANCE?

JARDIANCE can cause serious side effects, including:

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

- **Dehydration. JARDIANCE 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 JARDIANCE.** You may be at higher risk of dehydration if you:

- take medicines to lower your blood pressure, including diuretics (water pills)
- are on 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.

- **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
- **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 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 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 JARDIANCE?

JARDIANCE is a prescription medicine used to:

- reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure, when the heart cannot pump enough blood to the rest of your body.
- reduce the risk of further worsening of kidney disease, end-stage kidney disease (ESKD), death due to cardiovascular disease, and hospitalization in adults with chronic kidney disease.
- reduce the risk of cardiovascular death in adults with type 2 diabetes and who also have known cardiovascular disease.
- lower blood sugar (glucose) along with diet and exercise in adults and children who are 10 years of age and older with type 2 diabetes.

JARDIANCE 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).

JARDIANCE is not for use to lower blood sugar (glucose) in people with type 2 diabetes who have severe kidney problems, because it may not work.

JARDIANCE is not for people with polycystic kidney disease, or who are taking or have recently received certain types of immunosuppressive therapy to treat kidney disease. JARDIANCE is not expected to work if you have these conditions.

It is not known if JARDIANCE is safe and effective in children under 10 years of age.

Who should not take JARDIANCE?

Do not take JARDIANCE if you:

- are allergic to empagliflozin or any of the ingredients in JARDIANCE. See the end of this Medication Guide for a complete list of ingredients in JARDIANCE. Symptoms of a serious allergic reaction to JARDIANCE may include:
 - rash
 - raised, red areas on your skin (hives)
 - swelling of your face, lips, mouth, and throat that may cause difficulty in breathing or swallowing

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

What should I tell my healthcare provider before taking JARDIANCE?

Before taking JARDIANCE, 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 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 JARDIANCE before you have surgery. Talk to your healthcare provider if you are having surgery about when to stop taking JARDIANCE 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 JARDIANCE.
- are pregnant or plan to become pregnant. JARDIANCE may harm your unborn baby. If you become pregnant while taking JARDIANCE, 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. JARDIANCE 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 JARDIANCE. Do not breastfeed while taking JARDIANCE.

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

JARDIANCE may affect the way other medicines work, and other medicines may affect how JARDIANCE 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 JARDIANCE?

- Take JARDIANCE exactly as your healthcare provider tells you to take it.
- Take JARDIANCE by mouth 1 time in the morning each day, with or without food.
- Your healthcare provider will tell you how much JARDIANCE to take and when to take it. Your healthcare provider may change your dose if needed.
- Your healthcare provider may tell you to take JARDIANCE along with other diabetes medicines. Low blood sugar can happen more often when JARDIANCE is taken with certain other diabetes medicines. See **"What are the possible side effects of JARDIANCE?"**
- 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 JARDIANCE at the same time. Talk with your healthcare provider if you have questions about a missed dose.
- If you take too much JARDIANCE, 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 JARDIANCE, 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 JARDIANCE and during treatment as needed.

What are the possible side effects of JARDIANCE?

JARDIANCE may cause serious side effects, including:

- See **"What is the most important information I should know about JARDIANCE?"**
- **Serious urinary tract infections.** Serious urinary tract infections that may lead to hospitalization have happened in people who are taking JARDIANCE. 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).** In adults, if you take JARDIANCE with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher. In children 10 years of age and older, the risk for low blood sugar is higher with JARDIANCE even if you do not use another medicine that can also lower blood sugar. The dose of your sulfonylurea medicine or insulin may need to be lowered while you take JARDIANCE.
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 JARDIANCE. 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)
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- **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 JARDIANCE and call your healthcare provider right away or go to the nearest hospital emergency room. See **"Who should not take JARDIANCE?"**.

The most common side effects of JARDIANCE include:

- urinary tract infections
- yeast infections in females

These are not all the possible side effects of JARDIANCE. 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 JARDIANCE?

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

General information about the safe and effective use of JARDIANCE.

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

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

What are the ingredients in JARDIANCE?

Active Ingredient: empagliflozin

Inactive Ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, and microcrystalline cellulose. In addition, the film coating contains the following inactive ingredients: hypromellose, polyethylene glycol, talc, titanium dioxide, and yellow ferric oxide.

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For more information about JARDIANCE, including current prescribing information and Medication Guide, go to **www.jardiance.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.

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