# JARDIANCE FOR ADULTS WITHHEART FAILURE Jardiance (empagliflozin) tablets

## 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 who also have known cardiovascular disease
- lower blood sugar 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 in people with type 1 diabetes. It may increase their risk of diabetic ketoacidosis (increased ketones in the blood or urine).

JARDIANCE is not for use to lower blood sugar 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.

## **IMPORTANT SAFETY INFORMATION**

• raised, red areas on your skin (hives)

**Do not take** JARDIANCE if you are allergic to empagliflozin or any of the ingredients in JARDIANCE.

Symptoms of a serious allergic reaction may include:

• rash

• swelling of your face, lips, mouth, and throat that may cause difficulty in breathing or swallowing

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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.

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### **IMPORTANT SAFETY INFORMATION (cont'd)**

#### **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, and 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:

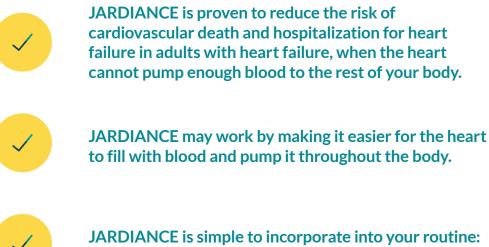
- nausea
- vomiting
- stomach-area (abdominal) pain

- tiredness
- ketones in your urine or blood

- trouble breathing



## **GET TO KNOW JARDIANCE**



JARDIANCE is simple to incorporate into your routine: one pill, taken in the morning.

## Talk to your doctor about adding JARDIANCE

## **IMPORTANT SAFETY INFORMATION (cont'd)**

• 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. Sudden worsening of kidney function has happened in people who are taking JARDIANCE.

You may be at a higher risk of dehydration if you:

- take medicines to lower your blood pressure. including water pills (diuretics)
- have kidney problems
- are 65 years of age or older

• are on a low salt diet

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, if you are sick or cannot eat, or start to lose liquids from your body from vomiting, diarrhea, or being in the sun too long.

- Vaginal yeast infection. Talk to your healthcare provider 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 skin around 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 healthcare provider if you have redness, itching or swelling of the penis, rash of the penis, foul smelling discharge from the penis, and/or 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.





## THERE'S A CARD THAT CAN SAVE YOU MONEY



With a JARDIANCE Savings Card, eligible commercially insured patients can pay as little as \$10\* per month for their 1- to 3-month prescription. And don't worry — we'll also automatically re-enroll you after 12 months as long as you still qualify.

SIGN UP AND SAVE AT <u>JARDIANCE.COM</u> or scan this QR code



## \*Terms & Conditions

Patients who meet the eligibility criteria may pay as little as \$10/month with a maximum savings up to \$175 per 30-day supply. Benefits not to exceed program expiration on December 31, 2024. In Massachusetts and California, the validity of this voucher and its use are subject to state law. Other state restrictions may apply. One card per patient, not transferable, and may not be used in combination with any other discount, coupon, rebate, free trial, or similar offer. **Card not accepted in Veterans Affairs pharmacies.** Program is not health insurance. Only valid for commercially insured patients in the 50 United States, DC, and Puerto Rico whose insurance policy provides coverage for JARDIANCE who are not reimbursed for the entire cost of the prescription. These are not the full program terms and conditions. **To view the full terms and conditions**, **please visit JARDIANCE.COM/savings**.





## You don't have to take on heart failure alone.

With the JARDIANCE Heart Your Heart Patient Support Program, we'll guide you with resources to help you care for your heart and stay on track with your treatment.



- A digital workbook with info on caring for your health
- Access to savings on out-of-pocket costs for eligible patients
- Answers to frequently asked questions about heart failure
- Resources to help keep you on track with treatment

## SIGN UP AT JARDIANCE.COM



or scan this QR code

## **IMPORTANT SAFETY INFORMATION (cont'd)**

- Serious urinary tract infections. Serious urinary tract infections can occur in people taking JARDIANCE and may lead to hospitalization. Tell your healthcare provider 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): In adults, if you take JARDIANCE with another medicine that can cause low blood sugar, such as sulfonylurea or insulin, your risk of low blood sugar is higher. In children 10 years of age and older, the risk for low blood sugar is higher with JARDIANCE regardless of use with another medicine that can also lower blood sugar. The dose of your sulfonylurea or insulin may need to be lowered. Symptoms of low blood sugar may include:
  - headache
    - weakness
- confusion irritability
- hunger fast heartbeat
- sweating

- drowsiness
- dizziness
- - shaking or feeling jittery
- 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 people who take JARDIANCE, and may lead to hospitalization, multiple surgeries, and death. Seek medical attention immediately if you have a fever or are feeling very weak, tired or uncomfortable (malaise), and you develop any of the following symptoms in the **Jardiance**<sup>®</sup> area between and around your anus and genitals: pain or tenderness, swelling, and redness of skin (erythema).



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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.

## **IMPORTANT SAFETY INFORMATION**

Do not take JARDIANCE if you are allergic to empagliflozin or any of the ingredients in JARDIANCE.

Symptoms of a serious allergic reaction 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.

### 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, and 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:** 

- vomiting
  - trouble breathing
- stomach-area (abdominal) pain
- 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. Sudden worsening of kidney function has happened in people who are taking JARDIANCE.

You may be at a higher risk of dehydration if you:

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

• are on a low salt diet

nausea

tiredness

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, if you are sick or cannot eat, or start to lose liquids from your body from vomiting, diarrhea, or being in the sun too long.

- Vaginal yeast infection. Talk to your healthcare provider 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 skin around 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 healthcare provider if you have redness, itching or swelling of the penis, rash of the penis, foul smelling discharge from the penis, and/or 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.



## **IMPORTANT SAFETY INFORMATION (cont'd)**

- Serious urinary tract infections. Serious urinary tract infections can occur in people taking JARDIANCE and may lead to hospitalization. Tell your healthcare provider 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): In adults, if you take JARDIANCE with another medicine that can cause low blood sugar, such as sulfonylurea or insulin, your risk of low blood sugar is higher. In children 10 years of age and older, the risk for low blood sugar is higher with JARDIANCE regardless of use with another medicine that can also lower blood sugar. The dose of your sulfonylurea or insulin may need to be lowered. Symptoms of low blood sugar may include:
  - headache
  - weakness drowsiness
    - dizziness
- confusion irritability
- hunger • fast heartbeat
- sweating • shaking or feeling jittery
- 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 people who take JARDIANCE, and may lead to hospitalization, multiple surgeries, and death. Seek medical attention immediately if you have a 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).
- 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.

The most common side effects of JARDIANCE include urinary tract infections and yeast infections in females.

These are not all the possible side effects of JARDIANCE. For more information, ask your healthcare provider or pharmacist.

## 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 dose
- are going to have surgery. Your healthcare provider may stop 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 dehvdrated
- 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. Tell your healthcare provider right away if you become pregnant during treatment with JARDIANCE
- are breastfeeding or are planning to breastfeed. JARDIANCE may pass into your breast milk and may harm your baby. 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.

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.

## Please see Prescribing Information and Medication Guide for JARDIANCE.

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