

A large yellow speech bubble graphic is centered on the page. It has a white outline and a white tail pointing towards the bottom left. Inside the bubble, the text is white. At the top right of the bubble, there is a small icon of a yellow megaphone with a red and blue top.

## Let's talk <sup>®</sup>Jardiance<sup>®</sup> (empagliflozin)

This booklet is designed to help answer your questions about JARDIANCE<sup>®</sup>, including what it does and how to take it.

### **KEEP IN MIND...**

While taking JARDIANCE<sup>®</sup>, continue with the diet and exercise plan recommended by your healthcare team

# Your treatment with JARDIANCE®



JARDIANCE® is used along with diet and exercise to improve blood sugar levels in adults with type 2 diabetes.

JARDIANCE® can be taken:

- alone, if you cannot take metformin
- with metformin
- with metformin and a sulfonylurea
- with pioglitazone  
(with or without metformin)
- with linagliptin and metformin
- with basal or prandial insulin  
(with or without metformin)

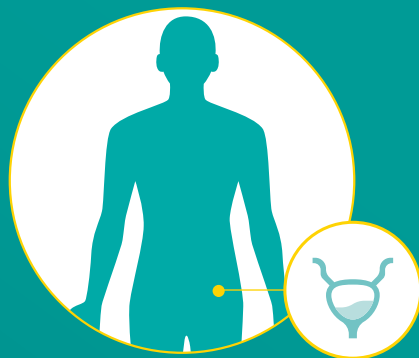


If you have type 2 diabetes and an increased cardiovascular risk (health problems due to your heart and blood vessels), JARDIANCE<sup>®</sup> can be used along with diet and exercise to lower your risk of dying from events related to your heart or blood vessels



## JARDIANCE® helps lower your blood sugar

With type 2 diabetes, blood sugar levels get too high. JARDIANCE® helps to remove excess sugar from the body through your urine.



## Interactions with JARDIANCE®

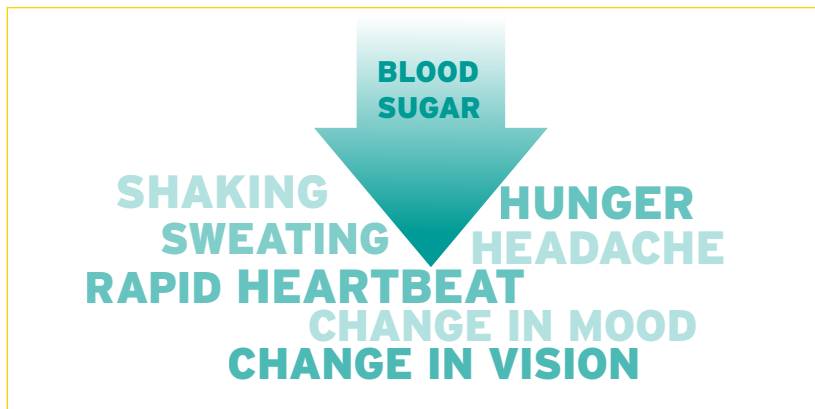
**Talk to your doctor or pharmacist about all the drugs you take. This includes prescription drugs, as well as those you buy yourself, and herbal supplements.**

Drugs that may interact with JARDIANCE® include medicines you take for diabetes, especially sulfonylurea medications or insulin.

Low blood sugar (hypoglycemia) may occur if you already take another medication to treat diabetes.

# Recognize the signs of low blood sugar

Be aware of signs that your blood sugar has dropped too low, including:



Contact your doctor or pharmacist if you experience these symptoms.

# Make JARDIANCE<sup>®</sup> part of your daily routine

Take JARDIANCE<sup>®</sup>:

- once a day
- at any time of day
- by mouth
- with or without food

**10 mg dose**  
(actual size)



**25 mg dose**  
(actual size)



Swallow whole. Do NOT cut or divide tablets.

The recommended starting dose is one 10 mg tablet, once daily. Your doctor may increase your dose to one 25 mg tablet, if needed to further control your blood sugar level.

**If you miss a dose, do not take a double dose of JARDIANCE®.**

If it is 12 hours or more until your next scheduled dose, take JARDIANCE® as soon as you can. Then take your next dose at the usual time.

If it is less than 12 hours until your next dose, skip the missed dose and take your next dose at the usual time.



**To avoid missing doses,  
try to take JARDIANCE®  
at the same time every day**

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## Possible side effects of JARDIANCE®

JARDIANCE® can cause side effects, including:

- dehydration (not enough fluids)
- unusual thirst
- passing more urine than usual or needing to pass more often
- itching
- rash
- straining or pain when passing urine

**If any of these affects you severely, tell your doctor or pharmacist.**

JARDIANCE® can cause abnormal blood test results. Your doctor will decide when to perform blood tests. JARDIANCE® may also cause abnormal kidney function and changes in the amount of cholesterol or fats in your blood. Your doctor will do blood tests to monitor how well your kidneys are working while you are taking JARDIANCE®. They may also check your blood fat levels and the amount of red blood cells in your blood.



Diabetic ketoacidosis (DKA) is a serious, life-threatening medical condition that may lead to death. DKA can happen even if your blood sugar is at normal or near normal levels, or if you have high blood glucose levels. During treatment with JARDIANCE<sup>®</sup>, DKA has happened in people who have type 1 or type 2 diabetes (JARDIANCE<sup>®</sup> should not be used in patients with type 1 diabetes), or in people with diabetes who were sick or who had surgery. DKA requires immediate treatment in a hospital. **Stop taking JARDIANCE<sup>®</sup> immediately and get immediate medical help if you have any of the symptoms described on page 14, even if your blood glucose levels are normal.**

JARDIANCE<sup>®</sup> may cause dizziness or lightheadedness. **Do not drive or use machines until you know how the medicine affects you.**

## Other possible serious side effects of JARDIANCE<sup>®</sup>



**CONTACT YOUR DOCTOR OR PHARMACIST**  
if you notice any of the serious side effects listed  
on the following pages

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# Urinary tract infection (UTI)

- Symptoms include a burning sensation when passing urine, pain in the pelvis or mid-back pain, or increased need to urinate



## TIPS

Consider the following tips to help reduce the risk of UTIs...

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- **Drink plenty of water** to help flush bacteria from the system
  - **Don't hold your urine;** empty your bladder completely when urinating
  - **Urinate immediately after having sex** to help flush away bacteria
  - **Wipe front to back** after urinating and passing stool, to help prevent the spread of bacteria
  - **Wear cotton underwear and loose-fitting clothes;** this encourages air flow, which helps keep the genitals dry

# Genital infections

JARDIANCE® increases the chance of getting a yeast infection of the penis or vagina. This is more likely in people who have had yeast infections in the past.

## Vaginal yeast infection

- Symptoms may include severe itching, burning, soreness, irritation and a whitish-gray cottage cheese-like discharge

## Yeast infection of the penis

- Symptoms include red, swollen, itchy head of penis, thick, lumpy discharge under foreskin, unpleasant odour, difficulty retracting foreskin, pain passing urine or during sex

**Consult a healthcare professional if your genital infection is severe.**

### What is a genital infection?

Genital infection, sometimes called **yeast infection**, occurs when there is an overgrowth of *Candida* – a form of yeast present in the body. This overgrowth may be caused by hormones, medicines or changes in the immune system.

**Wearing cotton underwear** is a simple approach to help reduce the risk of developing a yeast infection. But if you do develop one, there are **antifungal medications available**.

### **Low blood pressure**

- Symptoms may include dizziness, fainting and lightheadedness. These symptoms may occur when you move from lying down to sitting or standing up.

### **Kidney problems**

- Symptoms may include any change in the amount, frequency or colour (pale or dark) of urine

### **Inflammation of the pancreas (pancreatitis)**

- Symptoms may include abdominal pain; severe stomach pain that lasts and gets worse when you lie down; nausea, vomiting, fever



# Get immediate medical help if you notice the following side effects...

## **Volume depletion (loss of needed fluids from the body, dehydration, especially in people older than 75)**

- Symptoms may include dry or sticky mouth, headache, dizziness or urinating less often than normal

## **Allergic skin reactions**

- Symptoms may include rash, hives, swelling of your lips, face, throat or tongue that may cause difficulty in breathing or swallowing

## **Severe infection that spreads from urinary tract throughout body (sepsis)**

- Symptoms may include fever or low body temperature, chills, rapid breathing, rapid heartbeat, pain with urination, difficulty urinating, frequent urination

## **Acute kidney infection**

- Symptoms may include painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul-smelling urine, blood in urine

## Diabetic ketoacidosis (DKA)

- Symptoms may include increased levels of ketones in urine or blood, rapid weight loss, feeling sick or being sick, difficulty breathing or fast and deep breathing, feeling very thirsty, vomiting, stomach pain, nausea, loss of appetite, confusion, feeling unusually tired or sleepy, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat

### What is DKA?

DKA - an increased level of ketones in your blood or urine seen in tests - is a serious and life-threatening complication of diabetes that requires urgent hospitalization. Ketones are chemicals created by a breakdown of fat for energy.

DKA has been reported in people with type 2 diabetes, with normal or high blood sugar levels, who are treated with JARDIANCE® or with other sodium-glucose co-transporter 2 (SGLT2) inhibitors. Some cases of DKA have led to death.

**Stop taking JARDIANCE® immediately** and seek medical attention right away if you have symptoms of DKA - even if your blood sugar levels are normal.

JARDIANCE® should not be used in patients with type 1 diabetes. It should not be used to treat DKA or if you have a history of DKA.

### **Fournier's gangrene (a serious infection affecting soft tissue)**

Known also as necrotizing fasciitis of the perineum (area between and around the anus and genitals), Fournier's gangrene is a rare, but serious and potentially life-threatening infection that requires urgent treatment. It can affect both men and women with diabetes taking SGLT2 inhibitors.

If you experience tenderness, redness or swelling of the genitals or the area from the genitals back to the rectum, especially if you also have a fever or are feeling unwell, contact your doctor right away. These may be signs of Fournier's gangrene.

This is not a complete list of side effects. For any unexpected effects while taking JARDIANCE®, contact your doctor or pharmacist.

# Before using JARDIANCE<sup>®</sup>, talk to your doctor or pharmacist if you...

- Are older than 65 years of age
- Are under 18 years of age (JARDIANCE<sup>®</sup> is not recommended for use in patients under 18)
- Have type 1 diabetes (your body does not produce insulin). JARDIANCE<sup>®</sup> should not be used in patients with type 1 diabetes.
- Have or have had any kidney problems
- Have or have had any cases of liver disease
- Have heart disease or low blood pressure
- Are taking a medicine for high blood pressure or taking a water pill (used to remove excess water from the body)
- Are taking medicines to lower your blood sugar such as glyburide, gliclazide or glimepiride (sulfonylureas) or insulin. Taking JARDIANCE<sup>®</sup> with any of these medicines can increase the risk of having low blood sugar (hypoglycemia).
- Have intolerance to some milk sugars. JARDIANCE<sup>®</sup> tablets contain lactose.
- Are 85 years old or older as you should not start taking JARDIANCE<sup>®</sup>



- Have an increased chance of developing DKA, including if you:
  - Are dehydrated or suffer from excessive vomiting, diarrhea or sweating
  - Are on a very low carbohydrate diet
  - Have been fasting for a while
  - Are eating less or there is a change in your diet
  - Drink a lot of alcohol
  - Have/have had problems with your pancreas, including pancreatitis or surgery on your pancreas
  - Are going to have surgery and after surgery
  - Are hospitalized for major surgery, serious infection or serious medical illnesses
  - Have an acute illness
  - Have sudden reductions in insulin dose
  - Have a history of DKA

Your doctor may stop your JARDIANCE® if you are going to have a surgery and after surgery, or if you are hospitalized for a serious infection, a serious medical illness or a major surgery. Talk to your doctor about when to stop taking JARDIANCE® and when to start it again. They will also check for ketones in your blood and urine.

JARDIANCE® will cause your urine to test positive for sugar (glucose).



## You should not take JARDIANCE® if you...

- Have type 1 diabetes (a disease in which your body does not produce any insulin)
- Have DKA or a history of DKA
- Have severe kidney problems or you are on dialysis
- Have severe liver disease
- Are pregnant or planning to become pregnant. It is not known if JARDIANCE® will harm your unborn baby. Talk with your doctor about the best way to control your blood sugar while you are pregnant.
- Are breastfeeding or plan to breastfeed. It is not known if JARDIANCE® will pass into your breast milk. Talk to your doctor if you would like to breastfeed.
- Are allergic to empagliflozin or any of the other non-medical ingredients in the JARDIANCE® tablet

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**For complete safety information, please refer to the consumer leaflet you received with JARDIANCE®**

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# Managing your sick days



If you become sick or dehydrated (not enough fluids), you should talk to your healthcare provider.

You should also work with your healthcare provider to prepare a sick day management plan to use if you become ill.

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**Jardiance**<sup>®</sup>  
(empagliflozin)

JARDIANCE<sup>®</sup> is a registered trademark of Boehringer  
Ingelheim International GmbH, used under license.

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