



Let's talk JARDIANCE®

This handout is designed to help answer your questions about JARDIANCE $^{\otimes},$ including what it does and how to take it.

KEEP IN MIND...

While taking JARDIANCE[®], 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[®] 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 $^{\circ}$ 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.

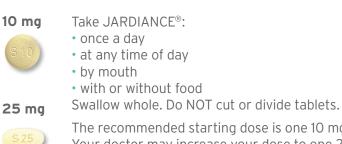
Low blood sugar (hypoglycemia) may occur if you already take another medication to treat diabetes.

Recognize the signs of low blood sugar



Contact your doctor or pharmacist if you experience these symptoms.

Make JARDIANCE® part of your daily routine



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.

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, and may check kidney function, blood fat levels, and the amount of red blood cells in your blood.

Diabetic ketoacidosis (DKA) is a serious medical condition with normal or high blood glucose levels. **Get immediate medical help if you have any** of the symptoms described below, even if your blood glucose levels are normal.

JARDIANCE[®] 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®



CONTACT YOUR DOCTOR OR PHARMACIST

if you notice any of the following serious side effects.

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

Genital infections

- Vaginal yeast infection: symptoms may include severe itching, burning, soreness, irritation, a whitish-gray cottage cheese-like discharge
- Yeast infection of the penis: 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 genital infection is severe.

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

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

Volume depletion (loss of needed fluids from the body, dehydration, especially in patients 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 difficulty breathing, feeling very thirsty, vomiting, stomach pain, nausea, loss of appetite, confusion, unusual tiredness, a sweet smell to the breath, a sweet or metallic taste in the mouth, or a different odour to urine or sweat

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

• Symptoms may include fever, feeling weak, tired or uncomfortable; tenderness, redness, or swelling in and around the genitals or anus

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

LIFESTYLE TIPS



Understanding UTIs and genital infections

Urinary tract infection (UTI)

Most UTIs are bred by bacteria called *E. coli*, which live in the bowel. *E. coli* enter the urinary tract, overcoming the body's natural defenses to cause infection. UTIs can also be caused by other types of bacteria, along with fungi and viruses.

Tips to help reduce the risk of UTIs...

- 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 infection

Sometimes called "**yeast infection**", genital infection occurs when there is an overgrowth of *Candida* – a form of yeast naturally present in the body. This overgrowth may be caused by medication, hormones, 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.**



If you are experiencing symptoms of UTI or genital infection, please consult a healthcare professional for treatment-related information.

Important safety information

You should not take JARDIANCE® if you:

- have type 1 diabetes (a disease in which your body does not make insulin)
- have diabetic ketoacidosis (a complication of diabetes) 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 breast-feeding or plan to breast-feed; it is not known if JARDIANCE[®] will pass into your breast milk. Talk to your doctor if you would like to breast-feed
- are allergic to empagliflozin or any of the other ingredients included in the JARDIANCE[®] formulation

Serious warnings and precautions

- Diabetic ketoacidosis (DKA) is a serious and life-threatening condition that requires urgent hospitalization. DKA has been reported in patients with type 2 diabetes mellitus (T2DM), with normal or high blood sugar levels, who are treated with JARDIANCE[®] and other sodium-glucose co-transporter 2 (SGLT2) inhibitors. Some cases of DKA have led to death
- Seek medical attention right away and stop taking JARDIANCE[®] immediately if you have any of the following symptoms (even if your blood sugar levels are normal): difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, feeling very thirsty, feeling unusually tired, a sweet smell to the breath, a sweet or metallic taste in the mouth or a different odour to urine or sweat
- JARDIANCE[®] should not be used in patients with type 1 diabetes
- JARDIANCE[®] should not be used to treat DKA or if you have a history of DKA

Before using JARDIANCE®, talk to your doctor or pharmacist if you:

- are older than 65 years of age
- have type 1 diabetes (your body does not make insulin);
 JARDIANCE[®] 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[®] with any of these medicines can increase the risk of having low blood sugar (hypoglycemia)

- have intolerance to some milk sugars, as JARDIANCE[®] tablets contain lactose
- \bullet are 85 years old or older, as you should not start taking JARDIANCE $^{\circ}$
- 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
 - drink a lot of alcohol
 - have/have had problems with your pancreas, including pancreatitis (inflamed pancreas) or surgery on your pancreas
 - are hospitalized for major surgery, serious infection or serious medical illnesses
 - have a history of diabetic ketoacidosis (DKA)

JARDIANCE®:

- is not recommended for use in patients under 18 years of age
- will cause your urine to test positive for sugar (glucose)
- may cause changes in the amount of cholesterol or fats in your blood
- may cause abnormal kidney function
 - your doctor will do blood tests to monitor how well your kidneys are working while you are taking 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
- may cause necrotizing fasciitis of the perineum (area between and around the anus and genitals)
 - this is a rare but serious and potentially life-threatening infection that can affect both men and women with diabetes taking SGLT2 inhibitors; it is also known as Fournier's gangrene and requires urgent treatment
 - 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
- may cause dizziness or lightheadedness
 - do not drive or use machinery until you know how the medicine affects you

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



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