

PART III: CONSUMER INFORMATION

Pr **Jardiance**[®]

empagliflozin tablets

This leaflet is part III of a three-part "Product Monograph" published when JARDIANCE was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about JARDIANCE. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

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

- alone, if you cannot take metformin;
- with metformin;
- with metformin and a sulfonylurea;
- with pioglitazone (with or without 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.

What it does:

JARDIANCE removes excess glucose from the body through the urine.

When it should not be used:

Do not take JARDIANCE if you:

- have type 1 diabetes (a disease in which your body does not produce any insulin);
- have diabetic ketoacidosis (DKA, 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 listed below.

What the medicinal ingredient is:

Empagliflozin

What the non-medicinal ingredients are:

Colloidal silicon dioxide, croscarmellose sodium,

hydroxypropyl cellulose, hypromellose, lactose monohydrate, magnesium stearate, macrogol, microcrystalline cellulose, titanium dioxide, talc, and yellow ferric oxide.

What dosage forms it comes in:

Tablets 10 mg and 25 mg.

WARNINGS AND PRECAUTIONS

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 you use JARDIANCE talk to your doctor or pharmacist if you:

- are older than 65 years of age;
- have type 1 diabetes (your body does not produce 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. JARDIANCE tablets contain lactose;
- are 85 years old or older as you should not start taking JARDIANCE;
- 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 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.

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

JARDIANCE may cause changes in the amount of cholesterol or fats in your blood.

JARDIANCE may cause abnormal kidney function. Your doctor will do blood tests to monitor how well your kidneys are working while you are taking JARDIANCE.

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.

Driving and using machines: JARDIANCE may cause dizziness or lightheadedness. Do not drive or use machines until you know how the medicine affects you.

INTERACTIONS WITH THIS MEDICATION

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. Discuss with your doctor how much of each medicine to take.

PROPER USE OF THIS MEDICATION

Follow the directions given to you by your doctor.

Take JARDIANCE:

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

Swallow whole. Do NOT cut or divide tablets.

Usual Adult dose:

Recommended starting dose: one 10 mg tablet a day.

Your doctor may increase your dose to one 25 mg tablet, if needed to further control your blood sugar level.

Overdose:

In case of drug overdose, contact a healthcare practitioner, hospital emergency department, or regional Poison Control Centre immediately, even if there are no symptoms.

Missed Dose:

Do not take a double dose of JARDIANCE.

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

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

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Side effects may include:

- dehydration;
- unusual thirst;
- passing more urine than usual or needing to pass more often;
- itching;
- rash;
- straining or pain when emptying the bladder.

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. They may check kidney function, blood fat levels and amount of red blood cells in your blood (hematocrit).

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 in the table below under DKA, even if your blood glucose levels are normal.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Get immediate medical help
		Only if severe	In all cases	
Very Common	Low blood sugar (hypoglycaemia): shaking, sweating, rapid heartbeat, change in vision, hunger, headache and change in mood.		✓	
Common	Urinary tract infection: burning sensation when passing urine, pain in the pelvis, or mid-back pain, or increased need to urinate.		✓	
	Genital infections: Vaginal yeast infection: severe itching, burning, soreness, irritation, and 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.	✓		
	Volume depletion (loss of needed fluids from the body, dehydration, especially in patients older than 75 years of age): dry or sticky mouth, headache, dizziness or urinating less often than normal.			✓

	Allergic skin reactions: rash, hives, swelling of your lips, face, throat or tongue that may cause difficulty in breathing or swallowing.			✓
Uncommon	Low Blood Pressure: dizziness, fainting, lightheadedness. May occur when you go from lying to sitting to standing up.		✓	
	Kidney problems: any change in the amount, frequency or colour (pale or dark) of urine.		✓	
	Severe infection that spreads from urinary tract throughout body (sepsis): fever or low body temperature, chills, rapid breathing, rapid heartbeat, pain with urination, difficulty urinating, frequent urination.			✓
	Acute kidney infection: painful, urgent or frequent urination, lower back (flank) pain, fever or chills, cloudy or foul smelling urine, blood in your urine.			✓
Rare	Diabetic Ketoacidosis (DKA): 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.			✓

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

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

HOW TO STORE IT

Store at room temperature (15 – 30°C).

Keep in a safe place out of reach from children.

MORE INFORMATION

If you want more information about JARDIANCE:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>), the manufacturer's website (<http://www.boehringer-ingenelheim.ca>), or by calling the manufacturer, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, extension 84633.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd. The information in this leaflet is current up to the time of the last revision date shown below, but more current information may be available from the manufacturer.

Last revised: April 16, 2018

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Co-promoted with:
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