

Jardiance	Updated Patient Information
mg, 25 mg 10	July 2021

Patient leaflet in accordance with the Pharmacists' Regulations (preparations) - 1986

This medicine is to be supplied upon physician's prescription only

Jardiance® 10 mg

Film-coated tablets

Each tablet of Jardiance 10 mg contains 10 mg empagliflozin.

Jardiance® 25 mg

Film-coated tablets

Each tablet of Jardiance 25 mg contains 25 mg empagliflozin.

For the list of inactive ingredients and allergens see section 2 'Important information about some of the ingredients of the medicine' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains summary information about this medicine. If you have any further questions, contact your physician or pharmacist. This medicine has been prescribed for treating your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. What is this medicine intended for?

Jardiance is indicated for:

- improvement of blood sugar level control in adults with type 2 diabetes, along with diet and exercise.
- reducing the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease.

Jardiance is not indicated for the treatment of type 1 diabetes or diabetic ketoacidosis.

Therapeutic group: SGLT2 (sodium-glucose co-transporter 2) inhibitors.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient empagliflozin or to any of the other ingredients that this medicine contains (please refer to section 6 – 'Additional information', for the list of inactive ingredients). Symptoms of a serious allergic reaction to Jardiance may include:
 - swelling of your face, lips, throat and other areas of your skin
 - difficulty with swallowing or breathing
 - raised, red areas on your skin (hives)

If you experience any of the symptoms on this list, stop taking Jardiance and call your physician right away or go to the nearest hospital emergency room.

- You suffer from severe renal impairment, end-stage renal disease, or you are on dialysis.

Special warnings regarding the use of the medicine

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Before taking Jardiance, tell your doctor about all of your medical conditions, including if:

- You suffer from a kidney problem.
- You suffer from liver problems.
- You have a history of infection of the vagina or penis.
- You have a history of urinary tract infections or problems with urination.
- You are about to have surgery. If you are about to have surgery, your physician may decide to stop Jardiance before you have surgery. Consult your physician when to stop taking Jardiance and when to start your treatment again.
- You are eating less, or there is a change in your diet.
- You have type 1 diabetes. Jardiance should not be used to treat people with type 1 diabetes.
- You are pregnant or plan to become pregnant - see section 2 'Pregnancy and breastfeeding'.
- You are breastfeeding or plan to breastfeed - see section 2 'Pregnancy and breastfeeding'.

In addition to this, tell your physician before you start using Jardiance or while you are on Jardiance, if:

- You have an acute illness such as flu, or a urinary tract infection, you are vomiting, have diarrhea or a fever, or if you are unable to eat or drink, are eating less or there is a change in your diet. Such situations may lead to dehydration. Your physician may ask you to stop taking Jardiance until you recover to prevent dehydration. Dehydration can damage your kidneys.
- You have or have had problems with your pancreas, including pancreatitis or surgery on your pancreas.
- You drink alcohol very often, or drink a lot of alcohol in a short space of time (binge drinking).
- You are being treated with insulin together with this medicine and there has been a sharp drop in your insulin dose.

These conditions may put you at risk of developing diabetic ketoacidosis. See the section 'Side Effects'.

Children and adolescents

It is not known whether this medicine is safe and effective in children. This medicine is not intended for children and adolescents under the age of 18.

Tests and follow up

- Diet and physical activity may help your body to use its blood sugar better. It is important to maintain the diet and physical activity plan recommended by the physician during the treatment with Jardiance.
Like other diabetes treatments, it is recommended to monitor the response to treatment periodically. The physician may recommend treatment with other medicines to achieve your treatment goals.
- Your physician may order blood tests to evaluate your renal function prior to beginning treatment with Jardiance and during the treatment with Jardiance.

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- **Urine test for glucose.** When taking Jardiance, you may have sugar in your urine, which will show up on a glucose urine test.
- **Diabetic foot:** It is important to check your feet regularly according to the recommendations given by your health care professional.

Other medicines and Jardiance

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the physician or the pharmacist, because Jardiance may affect the way some medicines work, and certain medicines may affect how Jardiance works. Especially tell your physician if you take any of the following medicines:

- **A medicine used to get rid of fluids from the body (diuretic).** Co-administration with Jardiance may result in increased urine volume and frequency of voids, which may increase the risk of dehydration. Possible symptoms of excessive loss of body fluids are described in section 4 – ‘Side effects’.
- **Other blood sugar lowering medicines (such as insulin or sulfonylurea).** Co-administration with Jardiance may increase the risk of low blood sugar levels (hypoglycemia). Therefore, when blood sugar lowering medicines (such as insulin or sulfonylurea) are used in combination with Jardiance, lower dosages of these medicines may be required to reduce the risk of low blood sugar level.

Know the medicines you take and keep a list of them to show your doctor and pharmacist when you get a new medicine.

Using this medicine and food

You can take this medicine with or without food.

Pregnancy and breastfeeding

Consult a physician or a pharmacist prior to beginning treatment, if you are pregnant, think that you may be pregnant, or plan to become pregnant, or if you are breastfeeding or plan to breastfeed.

Do not use Jardiance if you are pregnant. Jardiance may harm your unborn baby. If you become pregnant while you are taking Jardiance, tell your physician as soon as possible. Consult your physician about the best way to control your blood sugar while you are pregnant.

Do not use Jardiance if you are breastfeeding. Jardiance may pass into your breast milk and harm your baby. Consult your physician about the best way to feed your baby while you are taking Jardiance.

Driving and using machines

Jardiance has a minor influence on your ability to drive and use machines.

Taking this medicine in combination with medicines called sulfonylurea or with insulin can cause low blood sugar levels (hypoglycemia), which may cause symptoms such as shaking, sweating and change in vision, and may affect your ability to drive and operate machines.

Do not drive or use any tool or machine, if you suffer from dizziness during the treatment with Jardiance.

Important information about some of the ingredients of the medicine

Jardiance contains lactose (milk sugar). If the physician has told you that you have an intolerance to some sugars, contact the physician before taking this medicine.

This medicine contains less than 1 millimole of sodium (23 mg) per tablet so it is

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considered 'sodium free'.

3. How should you use the medicine?

Always use according to the physician's instructions. Check with the physician or the pharmacist if you are not sure about your dose or about how you should take this medicine.

The dosage and treatment will be determined only by the physician. **Do not exceed the recommended dose.**

- The standard initial dosage is usually one Jardiance 10 mg tablet once a day. The physician will decide whether to increase your dose to Jardiance 25 mg.
- Your dosage will be adjusted by the physician. Do not change the dose unless your physician has told you to.

Taking the medicine

- Swallow the tablet whole with water. There is no information about crushing/splitting/chewing.
- You may take the medicine with or without food.
- You may take the medicine once a day in the morning; try to take it at the same time of the day. This will help you to remember to take the medicine.
- Your physician may tell you to take Jardiance alone or along with other diabetes medicines. Low blood sugar can happen more often when Jardiance is taken with certain other diabetes medicines. See section 2 'Other medicines and Jardiance' and section 4 'Side effects', for more information.

If you have accidentally taken a higher dosage

If you have taken an overdose or a child has accidentally swallowed this medicine, refer immediately to a physician or to a hospital emergency room and bring the medicine package with you.

If you have forgotten to take the medicine

Take the dose as soon as you remember and the next dose at the usual time.

If it is time to take the next dose, skip the forgotten dose and take the next dose at the usual time. Do not take a double dose to compensate for the forgotten dose.

Persist with the treatment as recommended by the physician.

Even if your condition has improved, do not discontinue treatment with the medicine without consulting the physician.

If you stop taking the medicine

Do not stop taking the medicine without consulting the physician. If you stop taking the medicine, your blood sugar levels may increase.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, contact your physician or the pharmacist.

4. Side Effects

As with any medicine, use of Jardiance may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

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Important information regarding Jardiance:

Jardiance may cause serious side effects.

Contact a physician as soon as possible if you experience any of the following serious side effects:

- **Ketoacidosis (increased ketones in your blood or urine):**

Ketoacidosis has happened in people who have **type 1 diabetes or type 2 diabetes**, during treatment with Jardiance. Ketoacidosis has also happened in people with diabetes who vomited or who had surgery during treatment with Jardiance. Ketoacidosis is a serious condition, which must be treated in a hospital. Ketoacidosis can lead to death.

Ketoacidosis can happen with Jardiance even if your blood sugar is less than 250 mg/dL.

Stop taking Jardiance and consult your physician right away or go to the nearest emergency room if you get any of the following symptoms: nausea, vomiting, stomach-area (abdominal) pain, tiredness, and trouble breathing.

If you get any of these symptoms during treatment with Jardiance, if possible, check for ketones in your urine, even if your blood sugar is less than 250 mg/dL.

- **Dehydration**

Jardiance can cause some patients to become dehydrated (the loss of body fluids and salt). Dehydration may cause you to feel dizzy, faint, or weak, especially when you shift from sitting or lying down to standing up. There have been reports of sudden worsening of kidney function in people taking Jardiance.

You may be at higher risk of dehydration if you:

- take medicines to lower your blood pressure, including diuretics
- are on a low sodium (salt) diet
- have kidney problems
- are 65 years of age or older.

Talk to your physician about what you should do to prevent dehydration including how much fluid you should drink on a daily basis.

Talk to your physician **right away** if you reduce the amount of food you eat or the amount of liquid you drink, for example if you vomit and cannot eat, or start to lose liquids from your body, for example after vomiting, having diarrhea or being in the sun too long.

- **Talk to your physician as soon as possible if you notice any of the following side effects:**

redness, pain, tenderness or swelling of the area between and around your anus and genitals with fever over 38°C or feeling generally unwell and weak. These side effects could be signs of Fournier's gangrene, a rare but life-threatening bacterial infection in the tissue under the skin in the area between and around the anus and genitals. There are a number of reported cases of this side effect in women and men taking diabetes medicines that belong to the same group as Jardiance. This side effect may lead to hospitalization, may require surgery, and may lead to death. The symptoms of Fournier's gangrene can get worse quickly so it is **important to get medical help quickly if you get any of these symptoms.**

- **Serious urinary tract infections:**

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Serious urinary tract infections that may lead to hospitalization have happened in people who are taking Jardiance. Tell your physician 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 level (hypoglycemia).** If you are taking Jardiance with another medicine that can cause low blood sugar levels, such as insulin or sulfonylurea, your risk of suffering from low blood sugar level is increased. The dose of your insulin or sulfonylurea may need to be lowered while you take Jardiance.

Signs and symptoms of low blood sugar level may include irritability, sleepiness, dizziness, shaking, sweating, confusion, fast heartbeat, hunger, headache, weakness.

The physician will instruct you how to treat low blood sugar levels and what to do if any of the above signs appear. If symptoms of low blood sugar level appear, eat glucose tablets, a snack with high sugar content or drink fruit juice. Measure your blood sugar level if possible and rest.

- **Vaginal yeast infection. The symptoms of this are: vaginal odor, white or yellowish vaginal discharge (discharge may be lumpy or look like cottage cheese), vaginal itching.**
- **Yeast infection of the penis.** Swelling of the penis in uncircumcised patients may develop that makes it difficult to pull back the skin around the tip of the penis. Other signs of yeast infection of the penis include: redness, itching or swelling of the penis, rash on the penis, foul smelling discharge from the penis, pain in the skin around the penis.

Talk to your physician about what you should do if you get symptoms of a yeast infection of the vagina or penis. Your physician may suggest you use over-the-counter antifungal medicines. Talk to your doctor **right away** if these medicines do not help and your symptoms do not go away.

- **Allergic reactions (hypersensitivity).** Serious allergic reactions have occurred in patients who took Jardiance.

Symptoms of an allergic reaction may include:

- Swelling of the face, lips, throat, or other areas of your skin.
- Difficulty swallowing or breathing.
- Raised, red areas on your skin (hives).

If you experience any symptom on this list, stop taking Jardiance and **immediately** consult your physician or go to the nearest emergency room.

The most common side effects in patients taking Jardiance include:

- urinary tract infections
- yeast infections in females

Other common side effects:

- Low blood sugar level (hypoglycemia)
- Upper respiratory tract infections.
- Increased urination
- Changes in blood lipid profile.
- Joint pain.

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- Yeast infection of the penis.
- Nausea.
- Thirst.

Uncommon side effects:

- Decrease in blood volume. The signs of decrease in blood volume are:
 - Critical decrease in blood pressure.
 - Decrease in blood pressure.
 - Dehydration.
 - Blood pressure drop upon standing up from the sitting/lying position.
 - Fainting.

Side effects reported after marketing and whose frequency cannot be defined: ketoacidosis (see under "Serious side effects", above), inflammation of the kidney and renal pelvis (pyelonephritis), and sepsis following a urinary tract infection (urosepsis), swelling of the face, lips, throat (angioedema), skin reactions (such as rash or hives), acute kidney injury, necrotizing fasciitis.

If a side effect occurs, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health (MoH) by following the link "Reporting side effects of medication" on the MoH home page (www.health.gov.il) which links to the online form for reporting side effects, or by following the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Store the medicine below 30°C.
- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from your physician.
- Do not use the medicine after the expiration date (exp. date) that appears on the box and blister. The expiration date refers to the last day of that month.
- Do not use the medicine if the package is damaged.
- Do not discard medicines in the household trash or sink. Ask the pharmacist how to dispose of medicines which are no longer used by you. These means will help to protect the environment.

6. Additional information

- In addition to the active ingredient, the medicine also contains:
Lactose monohydrate, cellulose microcrystalline, hydroxypropylcellulose, croscarmellose sodium, colloidal anhydrous silica, magnesium stearate.
The tablet coating is composed of:
Hypromellose 2910, titanium dioxide, talc, macrogol 400, iron oxide yellow.

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- What does the medicine look like and what is the content of the package:
Jardiance 10 mg are film-coated, round, pale yellow, biconvex, bevel-edged tablets. "S 10" is imprinted on one side of the tablet and Boehringer Ingelheim company logo is imprinted on the other side.

Jardiance 25 mg are film-coated, oval, pale yellow, biconvex tablets. "S 25" is imprinted on one side of the tablet and Boehringer Ingelheim company logo is imprinted on the other side.
The tablets are packed in blisters. Each pack contains 7, 30, 60 or 90 film-coated tablets. Not all pack sizes may be marketed.
- Marketing authorization holder's name and address: Boehringer Ingelheim Israel Ltd., 89 Medinat Ha-Yehudim St., P.O.B. 4124, Herzeliya Pituach 4676672.
- Manufacturer's name and address: Boehringer Ingelheim Pharma, Ingelheim am Rhein, Germany.
- This leaflet was revised in August 2021 according to Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Jardiance 10 mg 154-22-34202-00
Jardiance 25 mg 154-23-34203-00