

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

The medicine is to be supplied upon physician’s prescription only

# Jardiance® 10 mg Film-coated tablets

# Jardiance® 25 mg Film-coated tablets

Each tablet of Jardiance 10 mg contains 10 mg empagliflozin.

Each tablet of Jardiance 25 mg contains 25 mg empagliflozin.

Jardiance 10 mg film-coated tablets

Inactive ingredients and allergens in the medicine - 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 the medicine.** This leaflet contains concise information about the medicine. If you have 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.

- What is the 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 10 mg** is intended to reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure.

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

Jardiance is not recommended for use to improve glycemic control in adults with type 2 diabetes mellitus and estimated glomerular filtration rate (eGFR) less than 30 ml/min/1.73m².

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

## 2. Before using this medicine


<ul style="list-style-type: none"><li>You are sensitive (allergic) to the active ingredient empagliflozin or to any of the additional ingredients that the 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: <ul style="list-style-type: none"><li>swelling of your face, lips, throat or other areas of your skin</li> <li>difficulty with swallowing or breathing</li> <li>raised, red areas on your skin (hives)</li></ul></li> <li>If you experience any of the symptoms on the list, stop taking Jardiance and contact your physician right away or go to the nearest hospital emergency room.</li> <li>You are on dialysis.</li></ul>
---

- Special warnings regarding the use of the medicine**  
**Before taking Jardiance, tell your physician about all of your previous 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 about 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, 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 can lead to dehydration. Your physician can 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 section ‘Side effects’.

**Children and adolescents**

	<b>Boehringer Ingelheim</b>
	<b>Jardiance® 10 mg Film-coated tablets</b>
	<b>Jardiance® 25 mg Film-coated tablets</b>

It is not known whether the 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 can 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 advisable to monitor the response to treatment periodically. The physician may recommend treatment with additional 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.
  - Urine test for glucose** - During the treatment with 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 can affect the way some medicines work, and certain medicines can 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.
  - Lithium.** Co-administration with Jardiance may reduce lithium concentration in your blood. Therefore, lithium levels in the blood should be monitored more frequently following initiation and dosage changes.

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

**Using the medicine and food**  
You can take this medicine with or without food.

- Pregnancy and breastfeeding**  
Consult a physician or a pharmacist prior to beginning using this medicine, if you are pregnant, think that you may be pregnant, 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 may 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 the medicine.

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

- The standard initial dosage is usually one Jardiance 10 mg tablet once daily in the morning, taken with or without food. If you have type 2 diabetes, the physician will decide whether to increase the dosage to Jardiance 25 mg.
- Your dosage will be adjusted by the physician. Do not change the dosage unless your physician has told you to .

**Do not exceed the recommended dose.**

- 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 can tell you to take Jardiance alone or along with other diabetes medicines. Low blood sugar level 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 the 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 the state of your health has improved, do not stop treatment with the medicine without consulting the physician.

**If you stop taking the medicine**  
Do not stop the treatment with 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 further questions regarding the use of the medicine, consult 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.

- Important information regarding Jardiance:**  
Jardiance can cause serious side effects.  
**Contact a physician as soon as possible if you experience any of the following serious side effects:**
- Ketoacidosis (increased ketones levels 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 medical condition which require treatment in a hospital. Ketoacidosis can lead to death. **Ketoacidosis may happen during treatment with Jardiance even if your blood sugar levels are less than 250 mg/dL. Stop using Jardiance and contact 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 the urine, even if your blood sugar levels are less than 250 mg/dL.

- Dehydration**  
Jardiance may 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 chance 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

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

- Contact 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 tissues 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 even may lead to death. The symptoms of Fournier’s gangrene may get worse quickly so it is **important to get medical help quickly if you get any of these symptoms.**
- Serious urinary tract infections:** 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 dosage 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** (infection of the glans only, or of the glans and foreskin in uncircumcised men). 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. Contact your physician **right away** if the use of these medicines does 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 can 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 from the list, stop taking Jardiance and contact your physician **immediately** or go to the nearest emergency room.

The most common side effects in patients taking Jardiance include:

- urinary tract infections
- yeast infections in females

*Additional common side effects:*

- low blood sugar level (hypoglycemia)
- upper respiratory tract infections
- increased urination
- changes in blood lipid profile
- joint pain
- 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)
- 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
- constipation

**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](http://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 tray. The expiration date refers to the last day of that month.

- Do not use this 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 measures 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.
- What does the medicine look like and what does the package contain: Jardiance 10 mg are round, pale yellow, biconvex, bevel-edged, film-coated tablets. They have “S 10” imprinted on one side and the Boehringer Ingelheim company logo on the other side.

Jardiance 25 mg are oval, pale yellow, biconvex, film-coated tablets. They have “S 25” imprinted on one side and the Boehringer Ingelheim company logo 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 November 2022 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