

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.

Each tablet of Jardiance 10 mg also contains 162.5 mg lactose.

Jardiance® 25 mg

Film-coated tablets

Each tablet of Jardiance 25 mg contains 25 mg Empagliflozin.

Each Jardiance 25 mg tablet also contains 113 mg lactose.

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

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) or have previously experienced serious sensitivity (allergy) 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).
- You suffer from severe renal impairment, end-stage renal disease, or you are on dialysis.

Special warnings regarding the use of the medicine

Before using Jardiance, tell your physician if:

- You suffer from a kidney problem.
- You suffer from liver problems.
- You have a history of urinary tract infections or problems with urination.

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

- You are going to have surgery.

- 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 following an illness, surgery, or 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

This medicine is not intended for children and adolescents under the age of 18.

Urine glucose test

The mechanism of action of the medicine leads to a positive result in urine glucose test.

Dehydration

Jardiance may cause dehydration (loss of body fluids and salts) in some patients.

Dehydration may cause dizziness, fainting or weakness, especially when you stand up from a sitting/lying down position.

Dehydration may increase the risk of hypotension. Ensure adequate intake of fluids during the day.

If you experience hypotension, inform the physician.

The risk of dehydration is higher if you:

- Suffer from low blood pressure.
- Take medicines to reduce your blood pressure, including diuretics.
- Are on a low sodium or salt diet.
- Suffer from kidney problems.
- Are 65 years old or older.

Patients with impaired renal function

During the period of treatment with Jardiance, it is recommended to perform frequent periodic tests for renal function. If your renal function is impaired, the physician may instruct you to stop using Jardiance.

It is recommended to evaluate renal function prior to beginning treatment with Jardiance and periodically during the treatment with Jardiance, especially in elderly patients or patients with impaired renal function.

Vaginal yeast infection

Women treated with Jardiance may suffer from vaginal yeast infection. The symptoms are:

- Vaginal odor.
- White or yellowish vaginal discharge.
- Vaginal itching.

Penile yeast infection

Men treated with Jardiance may suffer from yeast infection in the skin around the penis. The symptoms are:

- Redness, itching or swelling of the penis.
- Rash on the penis.
- Foul smelling discharge from the penis.
- Pain in the skin around the penis.

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.

- It is recommended to evaluate renal function prior to beginning treatment with Jardiance and periodically during the treatment with Jardiance, especially in elderly patients or patients with impaired renal function (see section 2 – “Patients with impaired renal function”).
- Diabetic foot: It is important to check your feet regularly according to the recommendations given by your health care professional.

If you are taking or have recently taken other medicines, including non-prescription medicines and food supplements, tell the physician or the pharmacist. In particular, inform the physician or the pharmacist if you are taking:

- **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.

Pregnancy and breastfeeding

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

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 too 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 are intolerant to some sugars, contact the physician before taking this medicine.

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.

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

- The standard initial dosage is 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.

When your body is under some types of stress, such as: fever, trauma (such as a car accident), infection or surgery, your medication may change. Tell your physician right away if you have any of these conditions and follow your physician's instructions

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.

Important information regarding Jardiance:

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 can be life-threatening, and may need to be treated in a hospital. **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 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.

- **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.

- **Kidney problems.** Sudden kidney failure has happened to people taking Jardiance. Consult your physician right away if you reduce the amount of food or liquid you drink following an illness or if you cannot eat or you start to lose liquids by vomiting, diarrhea or being in the sun too long.

- **Hypoglycemia (low blood sugar level).** If you are taking Jardiance with another medicine which may cause low blood sugar levels, such as insulin or sulfonylurea, your risk of suffering from low blood sugar levels is increased. See section 2- "Drug interactions" for additional information.

Possible signs of low blood sugar level are: irritability, sleepiness, dizziness, shaking, sweating, confusion, fast heartbeat, excessive 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.

- **Severe infection of the genitals.** A rare but severe bacterial infection which damages the tissue under the skin (necrotizing fasciitis) in the area between the anus and the genitals and around them (perineum). Necrotizing fasciitis has been reported in both men and women taking Jardiance. This inflammation may result in hospitalization, multiple surgeries, and even death. Please get medical treatment immediately if you develop a fever or feel very weak, tired or restless, in addition to one or more of the following symptoms in the area between your anus and your genitals and around them: pain or tenderness, swelling, redness of the skin.

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

Symptoms of allergic reactions may include:

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

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

- **Increased blood lipid levels.**

In addition, other side effects may appear, such as:

- Vaginal yeast infections. The signs of vaginal yeast infections include:
 - Vaginal odor.
 - White or yellowish vaginal discharge (the discharge may be lumpy or look like cottage cheese).
 - Vaginal itching.
- Penile yeast infection, especially in uncircumcised patients and patients with recurrent and chronic infections. In uncircumcised patients, penile swelling may occur, causing difficulties pulling the skin backwards around the tip of the penis. The signs of penile yeast infections 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.

Discuss with the physician what you should do if you suffer from vaginal or penile yeast infection. The physician may recommend treatment with anti-fungal medications. If treatment with these medications does not help, contact the physician again.

Other common side effects:

- Upper respiratory tract infections.
- Changes in blood lipid profile.
- Joint pain.
- 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.
- Need to urinate often and right away.

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), 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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMe>

5. How to store the medicine?

- Store the product 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.
- 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: Boehringer Ingelheim Israel Ltd., 89 Medinat Ha-Yehudim St., P.O.B. 4124, Herzeliya Pituach 4676672.
- Manufacturer: Boehringer Ingelheim Pharma, Ingelheim am Rhein, Germany.
- This leaflet is formatted according to Ministry of Health guidelines. This leaflet was checked and approved by the Ministry of Health in February 2017 and revised in November 2018 in accordance with Ministry of Health guidelines.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health:
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Jardiance 25 mg 154-23-34203-00