

Package leaflet: information for the patient

Jardiance 10 mg film-coated tablets
Jardiance 25 mg film-coated tablets
empagliflozin

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed only for you. It may harm others, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

Contents of this leaflet

1. What is Jardiance and what is it used for?
2. When should you not take this medicine or be extra careful with it?
3. How do you take this medicine?
4. Possible side effects
5. How do you store this medicine?
6. Contents of the pack and other information

1. What is Jardiance and what is it used for?

What is Jardiance?

Jardiance contains the active substance empagliflozin.

Jardiance is part of a group of medicines called sodium-glucose co-transporter-2 (SGLT2) inhibitors.

What is Jardiance used for?

Diabetes mellitus type 2

- Jardiance is used to treat type 2 diabetes in adults and children aged 10 years and older that cannot be controlled by diet and exercise alone.
- Jardiance can be used without other medications in patients who cannot take metformin (another antidiabetic medicine).
- Jardiance can also be used with other medications for the treatment of diabetes. These can be medicines taken orally or administered by injection, such as insulin.

Jardiance works by blocking the SGLT2 protein in the kidneys. This removes blood sugar (glucose) through your urine. As a result, Jardiance lowers the amount of sugar in your blood.

This medicine can also help prevent heart disease in patients with type 2 diabetes mellitus.

Continue with your diet plan and keep exercising. It is important to continue as discussed with your doctor, pharmacist, or nurse.

Heart failure

- Jardiance is used to treat heart failure in adult patients who experience symptoms due to reduced heart function.

Chronic kidney disease

- Jardiance is used to treat chronic kidney disease in adult patients.

What is type 2 diabetes?

Type 2 diabetes is a disease caused by both your genetic predisposition (genes) and your lifestyle. If you have type 2 diabetes, your pancreas does not produce enough insulin to control the level of glucose in your blood, and your body is unable to use its own insulin effectively. This results in a high concentration of glucose in your blood, which can lead to medical problems such as heart disease, kidney disease, blindness, and poor blood circulation in your arms and legs.

What is heart failure?

Heart failure occurs when the heart is too weak or stiff and cannot function properly. This can lead to serious medical problems and hospitalization. The most common features of heart failure are shortness of breath, always feeling tired or very tired, and swelling of the ankles.

Jardiance helps protect your heart from becoming weaker and reduces your symptoms.

What is chronic kidney disease?

Chronic kidney disease is a long-term illness. It can be caused by other diseases such as diabetes and high blood pressure. It is also possible that your own body's defense system (the immune system) attacks the kidneys.

If you have chronic kidney disease, your kidneys gradually fail to clean and filter the blood. This can lead to serious medical problems such as swollen legs, heart failure, or the need for hospital treatment.

Jardiance helps protect your kidneys from losing their function.

2. When should you not take this medicine or be extra careful?

When should you not take this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?

Contact your doctor or the nearest hospital immediately:

Ketoacidosis (acidification of the blood)

- if you experience symptoms such as rapid weight loss, nausea or vomiting, abdominal pain, excessive thirst, rapid and deep breathing, confusion, unusual drowsiness or fatigue, a sweet smell on your breath, a sweet or metallic taste in your mouth, or a different smell to your urine or sweat, contact a doctor or the nearest hospital immediately. These symptoms may indicate 'ketoacidosis' – a serious, sometimes life-threatening condition where laboratory tests show an increased concentration of

'ketone bodies' in your blood or urine. The risk of developing ketoacidosis may be increased if you eat or drink little or nothing for a long time, consume a lot of alcohol, are dehydrated, have a sudden reduction in insulin dosage, or have a greater need for insulin due to major surgery or serious illness.

Do you think you have ketoacidosis? Then contact your doctor or the nearest hospital immediately. Stop taking this medicine until you have consulted your doctor.

Contact your doctor, pharmacist, or nurse before taking this medicine and during treatment:

- if you have 'type 1 diabetes'. This type usually starts when you are young and your body does not produce insulin. You should not use Jardiance if you have type 1 diabetes.
- if you have severe kidney problems. Your doctor may tell you to take 1 tablet of 10 mg once a day. Your doctor may also ask you to take another medicine (see also section 3, 'How to take this medicine').
- if you have severe liver problems – your doctor may ask you to take another medicine.
- if you are at risk of dehydration, for example:
 - if you are vomiting, have diarrhea or fever, or if you cannot eat or drink
 - if you are taking medicines that increase urine production (diuretics) or lower blood pressure
 - if you are 75 years or older.

Possible symptoms are listed in section 4 under 'Dehydration'. Your doctor may ask you to stop taking Jardiance until you have recovered to prevent loss of too much body fluid. Ask about ways to prevent dehydration.

- if you have a severe kidney or urinary tract infection with fever. Your doctor may ask you to stop taking Jardiance until you have recovered.

Contact your doctor immediately if you experience a combination of symptoms such as pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus, with fever or a general feeling of being unwell. These symptoms may indicate a rare but serious or even life-threatening infection called necrotizing fasciitis of the perineum or Fournier's gangrene, which damages the tissue under the skin. Fournier's gangrene requires immediate treatment.

Foot care

As with all diabetes patients, it is important for you to regularly check your feet and follow any foot care advice from your healthcare provider.

Kidney function

Your kidneys should be checked before starting treatment and during the use of this medicine.

Urine glucose (sugar in your urine)

Due to the way this medicine works, your urine will test positive for sugar while you are using this medicine.

Children and adolescents up to 18 years

Children aged 10 years and older with type 2 diabetes can use Jardiance. There is no data available for children under 10 years.

Are you, or is your child, under 18 years old and need to be treated for heart failure or chronic kidney damage? Then the use of Jardiance is not recommended. No research has been conducted in these patients.

Are you taking any other medicines?

Are you taking any other medicines besides Jardiance, have you recently done so, or is there a possibility that you will soon take other medicines? Then tell your doctor or pharmacist.

It is important to tell your doctor:

- if you are taking medicines that increase urine production (diuretics). Your doctor may ask you to stop taking Jardiance. Possible symptoms of losing too much fluid from your body are listed in section 4.
- if you are taking other medicines that lower the amount of sugar in your blood, such as insulin or a 'sulfonylurea'. Your doctor may want to reduce the dosage of these other medicines to prevent you from getting a low blood glucose level (hypoglycemia).
- if you are taking lithium. Jardiance can lower the amount of lithium in your blood.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Do not use Jardiance if you are pregnant. It is not known if Jardiance is harmful to the unborn child. Do not use Jardiance if you are breastfeeding. It is not known if Jardiance passes into breast milk.

Driving and using machines

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

Taking this medicine in combination with medicines called 'sulfonylureas' or with insulin can cause a low blood glucose level (hypoglycemia). This can lead to symptoms such as shaking, sweating, and changes in vision, and it can affect your ability to drive and use machines. Do not drive or use tools or machines if you feel dizzy while using Jardiance.

Jardiance contains lactose

Jardiance contains lactose (milk sugar). If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before using this medicine.

Jardiance contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, which means it is essentially 'sodium-free'.

3. How do you take this medicine?

Always take this medicine exactly as your doctor has told you. If you are unsure about the correct use, contact your doctor or pharmacist.

How much should you take?

- It is recommended that you start taking Jardiance 1 tablet of 10 mg once a day. If you have type 2 diabetes mellitus, your doctor will decide whether to increase the dose to 1 tablet of 25 mg once a day, if necessary to control your blood sugar.

- Your doctor may limit the dose to 1 tablet of 10 mg once a day if you have kidney problems.
- Your doctor will prescribe the strength that is right for you. Do not change the dose unless your doctor has told you to.

How do you take this medicine?

- Swallow the tablet whole with water.
- You can take the tablet with or without food.
- You can take the tablet at any time of the day. However, try to take it at the same time every day. This will help you remember to take it.

If you have type 2 diabetes mellitus, your doctor may prescribe Jardiance together with another antidiabetic medicine. Remember to take all medicines as directed by your doctor to achieve the best result for your health.

A suitable diet plan and exercise help your body use blood sugar better. It is important to continue with the diet plan and exercise recommended by your doctor while using Jardiance. Have you taken too much of this medicine?

If you have taken too much Jardiance, contact a doctor immediately or go directly to a hospital. Take the medicine box with you.

Have you forgotten to take this medicine?

What you should do if you forget to take a tablet depends on how long it is until your next dose.

- If it is 12 hours or more until your next dose, take Jardiance as soon as you remember. Then take the next dose at the usual time.
- If it is less than 12 hours until the next dose, you should not take the missed dose. Then take the next dose at the usual time.
- Do not take a double dose of Jardiance to make up for a forgotten dose.

If you stop taking this medicine

Do not stop taking Jardiance without first consulting your doctor. Stop taking Jardiance if you think you have ketoacidosis (see 'Ketoacidosis' under 'When should you be extra careful with this medicine?'). If you have type 2 diabetes mellitus and stop taking Jardiance, your blood sugar level may rise.

Do you have any other questions about the use of this medicine? Then contact your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Contact a doctor or the nearest hospital immediately if you have any of the following side effects:

Severe allergic reaction, occurs sometimes (may occur in up to 1 in 100 people)

Possible signs of a severe allergic reaction may include:

- swelling of the face, lips, mouth, tongue, or throat, which may cause difficulty in breathing or swallowing.

Ketoacidosis (acidification of the blood), occurs sometimes (may occur in up to 1 in 100 people)

These are the signs of ketoacidosis (see also section 2 'When to be extra careful with this medicine?'):

- an increased level of 'ketone bodies' in your blood or urine
- rapid weight loss
- nausea or vomiting
- abdominal pain
- feeling very thirsty
- rapid and deep breathing
- confusion
- unusual drowsiness or tiredness
- a sweet smell of your breath, a sweet or metallic taste in your mouth, or a different smell of your urine or sweat.

These symptoms can occur regardless of blood sugar level. Your doctor may decide to temporarily or permanently stop your treatment with Jardiance.

Contact your doctor as soon as possible if you experience the following side effects:

Low blood sugar level (hypoglycemia), very commonly observed (may occur in more than 1 in 10 people)

If you take Jardiance with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, the chance of getting low blood sugar is higher. The symptoms of low blood sugar can include:

- shaking, sweating, feeling very anxious or confused, rapid heartbeat
- excessive hunger, headache.

Your doctor will tell you how to treat low blood sugar levels and what to do if you experience any of the aforementioned symptoms. If you have symptoms of low blood sugar, eat glucose tablets, a sugary snack, or drink fruit juice. If possible, measure your blood sugar and rest.

Urinary tract infection, commonly observed (may occur in up to 1 in 10 people) The symptoms of a urinary tract infection are:

- burning sensation during urination
- urine appears cloudy
- pain in the pelvis or pain in the lower back (when kidneys are infected).

An urge to urinate or more frequent urination may be due to the mechanism of action of Jardiance, but can also be symptoms of a urinary tract infection. If you notice an increase in such symptoms, you should also contact your doctor.

Dehydration, very commonly observed (may occur in more than 1 in 10 people)

The symptoms of dehydration are not specific, but may include:

- unusual thirst
- lightheadedness or dizziness upon standing

- fainting or loss of consciousness.

Other side effects while taking Jardiance:

Common

- genital yeast infection (thrush)
- urinating more than usual or needing to urinate more frequently
- itching
- skin rash or red skin – this may itch and be accompanied by bumps, discharge, or blisters
- thirst
- blood test may show an increase in the levels of fats in the blood (cholesterol)
- constipation.

Sometimes

- hives
- difficulty or pain when emptying the bladder
- blood test may show a decrease related to kidney function (creatinine or urea)
- blood test may show an increase in the number of red blood cells in your blood (hematocrit).

Rarely

- necrotizing fasciitis of the perineum or Fournier's gangrene, a severe soft tissue infection of the genitals or the area between the genitals and the anus.

Very rarely

- inflammation of the kidneys (tubulo-interstitial nephritis).

Reporting side effects

If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How do you store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find it on the blister pack and on the box after 'EXP'. It includes a month and a year. The last day of that month is the expiry date.

There are no special storage conditions for this medicine.

Do not use this medicine if you notice that the packaging is damaged or shows signs of tampering.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed responsibly and do not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

- The active substance in this medicine is empagliflozin.
Each tablet contains 10 mg or 25 mg of empagliflozin.
- The other ingredients in this medicine are:
tablet core: lactose monohydrate (see end of section 2 under 'Jardiance contains lactose'), microcrystalline cellulose, hydroxypropyl cellulose, croscarmellose sodium (see end of section 2 under 'Jardiance contains sodium'), colloidal anhydrous silica, magnesium stearate
film coating: hypromellose, titanium dioxide (E171), talc, macrogol (400), yellow iron oxide (E172).

What does Jardiance look like and what is in a pack?

Jardiance 10 mg film-coated tablets are round, light yellow, biconvex, and have a beveled edge. They have the inscription 'S10' on one side and the Boehringer Ingelheim logo on the other side. The tablets are 9.1 mm in diameter.

Jardiance 25 mg film-coated tablets are oval, light yellow, and biconvex. They have the inscription 'S25' on one side and the Boehringer Ingelheim logo on the other side. The tablet is 11.1 mm long and 5.6 mm wide.

Jardiance tablets are available in perforated PVC/aluminum unit dose blister packs. The pack sizes are 7 x 1, 10 x 1, 14 x 1, 28 x 1, 30 x 1, 60 x 1, 70 x 1, 90 x 1, and 100 x 1 film-coated tablets.

Not all pack sizes may be marketed in your country.

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This leaflet was last approved in {month YYYY}.

More information about this medicine is available on the website of the European Medicines Agency: <http://www.ema.europa.eu>.