

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**



Jardiance® 10 mg

Jardiance® 25 mg

film-coated tablets

empagliflozin

Contains sugar (lactose monohydrate)

Read all of this leaflet carefully before you start taking JARDIANCE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- JARDIANCE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What JARDIANCE is and what it is used for
2. What you need to know before you take JARDIANCE
3. How to take JARDIANCE
4. Possible side effects
5. How to store JARDIANCE
6. Contents of the pack and other information

Do not take JARDIANCE if you have 'type 1' diabetes.

JARDIANCE is not used to control body weight.

There have been reports of 'metabolic acidosis' or 'ketoacidosis' in people with diabetes mellitus taking JARDIANCE, which is life threatening and needs to be treated in hospital. Cases of ketoacidosis have also been reported in people without diabetes mellitus.

If you have any symptoms of metabolic acidosis such as feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat, you must immediately contact a doctor or the nearest hospital in order to be assessed for metabolic acidosis, even if your blood glucose level is below 11 mmol/L.

Please refer also to 'Warnings and precautions'.

1. What JARDIANCE is and what it is used for

The active ingredient in JARDIANCE, is empagliflozin, which works by blocking a protein in the kidneys called sodium glucose cotransporter 2 (SGLT2).

If you have 'type 2 diabetes' and have too much sugar in your blood, JARDIANCE removes excess sugar from your body through the urine.

JARDIANCE can also affect other organs and functions in your body (e.g., blood vessels, the heart and kidneys) to provide cardiovascular and kidney benefits for people with or without type 2 diabetes.

What JARDIANCE is used for

Type 2 diabetes mellitus

JARDIANCE is used to treat type 2 diabetes in adults (aged 18 years and older) to improve blood sugar (glucose) control together with diet and exercise.

JARDIANCE can be used alone or can also be taken with other medicines used to lower your blood sugar. These may be medicines taken by mouth or administered by injection such as insulin.

JARDIANCE is also used in adults with 'type 2 diabetes' with an increased cardiovascular risk (health problems due to your heart and blood vessels), to lower the risk of dying from a heart attack or other events related to your heart or blood vessels, or to reduce the risk of being admitted to hospital for heart failure.

Because of how JARDIANCE works, your urine will test positive for sugar while you are taking JARDIANCE. The effectiveness of your blood sugar control cannot therefore be assessed by using the presence of sugar (glucose) in your urine.

Heart failure

JARDIANCE is used to treat heart failure in adults with or without type 2 diabetes, to reduce the risk of cardiovascular death and to reduce hospitalisation for heart failure. JARDIANCE also helps to slow down the worsening of kidney function.

Heart failure occurs when your heart is too weak or stiff and cannot work properly. This can lead to serious medical problems and need for hospital care. The most common symptoms of heart failure are feeling breathless, feeling tired or very tired all the time and ankle swelling.

JARDIANCE helps protect your heart from getting weaker and improves your symptoms.

Chronic kidney disease

JARDIANCE is used in adults with chronic kidney disease to reduce the risk of:

- progression of your kidney disease or death due to problems with your heart or blood vessels.
- hospitalisation from any cause.

Chronic kidney disease is a long-term condition. It might be caused by other diseases such as diabetes and high blood pressure or even by your own immune system attacking the kidneys. When you have chronic kidney disease, your kidneys may gradually lose their ability to clean and filter your blood properly. This can lead to serious medical problems such as swollen legs, heart failure or need for hospital care. JARDIANCE helps protect your kidneys from losing their function.

2. What you need to know before you take JARDIANCE

Do not take JARDIANCE

- if you are hypersensitive (allergic) to empagliflozin or any of the other ingredients of JARDIANCE film-coated tablets (listed in section 6).
- if you have type 1 diabetes.
- if you have increased levels of ketone bodies in your urine or blood (see 'Warnings and precautions').
- if you are pregnant or if you are breastfeeding your baby.

Do not take JARDIANCE if the above applies to you. If you are not sure, talk to your doctor or other healthcare provider before taking JARDIANCE.

Warnings and precautions

Stop taking JARDIANCE and contact a doctor or the nearest hospital immediately if you:

- experience any of the following symptoms (even if your blood sugar levels are normal): rapid weight loss, feeling sick or being sick, stomach pain, excessive thirst, fast and deep breathing, confusion, unusual sleepiness or tiredness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat.

These symptoms could be a sign of ‘ketoacidosis’ a problem you can get because of increased levels of ‘ketone bodies’ in your urine or blood seen in tests. The risk of developing ‘ketoacidosis’ may be increased with prolonged fasting, a very low carbohydrate diet, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness, or if you have or have had problems with your pancreas including pancreatitis or surgery on your pancreas.

Ketoacidosis is a serious problem which is life threatening and needs to be treated in a hospital. It has been reported in people with diabetes taking JARDIANCE, regardless of blood sugar level. Although ketoacidosis is less likely to occur in people without diabetes, cases have been reported.

Talk to your doctor, pharmacist or nurse before taking JARDIANCE, or during treatment with JARDIANCE if you:

- are taking or using any other diabetes medicine to lower your blood sugar. If you are also taking another diabetes medicine known as a ‘sulphonylurea’, or if you are injecting insulin, your doctor may want to reduce your dose of the ‘sulphonylurea’ or insulin when you take it together with JARDIANCE in order to avoid low blood sugar (hypoglycaemia). Please refer to possible signs of low blood sugar listed under ‘Driving and using machines’ and in section 4 ‘Possible side effects’.
- have serious kidney problems or are on renal dialysis. Your doctor may limit your dose to 10 mg once a day or ask you to take a different medicine (see-also section 3, ‘How to take JARDIANCE’).

Your kidney function should be assessed before you start taking JARDIANCE, at least 6-monthly during treatment, and also if you are taking JARDIANCE together with metformin, another medicine used to control blood sugar.

- have liver problems.
- are 75 years old or older or have problems with low blood pressure or if you are taking medicine to treat high blood pressure and/or diuretics (medicine used to remove water from the body sometimes also known as ‘water tablets’) as increased passing of urine due to the medicine may affect the fluid balance in your body and increase your risk of dehydration. Please refer to possible signs listed in section 4.
- are sick or if you have diarrhoea or fever or if you are not able to eat or drink. These can cause dehydration (excessive loss of body fluid). To prevent the excessive loss of body fluid, your doctor may ask you to stop taking JARDIANCE until you have recovered.
- have a history of urinary tract infections or have a serious infection of the kidneys or urine. Your doctor may ask you to stop taking JARDIANCE until you have recovered.

Talk to your doctor immediately if you:

- develop a combination of symptoms of pain, tenderness, redness, or swelling of the genitals or the area between the genitals and the anus with fever or are feeling generally unwell. These symptoms could be a sign of a rare but serious or even life threatening infection, called necrotising fasciitis of the perineum or Fournier's gangrene which destroys the tissue under the skin. Fournier's gangrene has to be treated immediately.
- have symptoms of genital burning, redness, pain and discharge which may be signs of a genital infection.

Children and adolescents

JARDIANCE is not recommended for children and adolescents under 18 years of age.

Other medicines and JARDIANCE

Always tell your healthcare provider if you are taking any other medicine (this includes all complementary or traditional medicines).

In particular, you should tell your doctor if you are taking:

- other medicines that lower the amount of sugar in your blood such as a 'sulphonylurea' or if you are injecting insulin. Your doctor may want to lower the dose of these other medicines, to prevent you from getting low blood sugar levels (hypoglycaemia).
- a medicine used to remove water from your body by increasing your urine production (called a 'diuretic', or sometimes called a 'water tablet'). Your doctor may ask you to stop taking JARDIANCE. Possible signs of losing excessive fluids from your body are listed in section 4.
- lithium, because JARDIANCE can lower the amount of lithium in your blood.

JARDIANCE with food and drink

You can take JARDIANCE with or without food.

Pregnancy and breastfeeding

You must not take JARDIANCE if you are pregnant.

Do not take JARDIANCE if you are breastfeeding.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking JARDIANCE.

Driving and using machines

Do not drive or use any tools or machines if you feel dizzy while taking JARDIANCE.

It is not always possible to predict to what extent JARDIANCE may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which JARDIANCE affects you.

Taking JARDIANCE in combination with other diabetes medicine called a 'sulphonylurea' or insulin can cause blood sugar levels which are too low (hypoglycaemia), which may affect your ability to drive and use machines.

If you experience symptoms of low blood sugar such as shaking, sweating, anxiety, blurred vision, tingling lips, paleness, mood change or confusion while taking JARDIANCE do not drive or use machines and contact your healthcare provider immediately.

JARDIANCE contains lactose

JARDIANCE contains lactose (milk sugar). If you have the rare hereditary conditions of lactose or galactose intolerance you should not take JARDIANCE.

3. How to take JARDIANCE

Do not share medicines prescribed for you with any other person.

Follow your healthcare provider's directions carefully.

Always take JARDIANCE exactly as your doctor has told you. Do not take more or less tablets and do not take them more often than recommended. Check with your doctor if you are not sure.

Type 2 Diabetes

The recommended starting dosage of JARDIANCE is one 10 mg tablet once a day. Your doctor will decide whether to increase your dose to 25 mg once a day if your blood glucose is not adequately controlled with a dose of 10 mg per day, or may limit your dose to 10 mg once daily if you have severe kidney problems.

Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you to.

Your doctor may prescribe JARDIANCE together with other diabetes medicines. Remember to take all medicines as directed by your doctor to achieve the best results for your health. Check your blood sugar as your healthcare professional advises you to.

Appropriate diet and exercise can help your body use its blood sugar better. It is important to stay on the diet and exercise program recommended by your healthcare provider while taking JARDIANCE.

Heart Failure or Chronic Kidney Disease

The dose of JARDIANCE is one 10 mg tablet once a day.

Taking this medicine

Swallow the tablet whole with water.

You can take JARDIANCE with or without food.

You can take the tablet at any time of the day. However, try to take it at the same time each day. This will help you to remember to take it.

Continue to take JARDIANCE as long as your doctor prescribes it.

If you have the impression that the effect of JARDIANCE is too strong, or too weak, talk to your doctor, pharmacist or nurse.

If you take more JARDIANCE than you should

In the event of overdosage or accidental intake, consult your doctor or pharmacist immediately. If neither is available, contact the nearest hospital or poison centre.

If you forget to take JARDIANCE

If you forget to take a dose of JARDIANCE, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose. Never take two doses on the same day.

If you stop taking JARDIANCE

Do not stop taking JARDIANCE without first consulting your doctor.

If you have type 2 diabetes, your blood sugar levels may increase when you stop taking JARDIANCE.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

JARDIANCE can have side effects.

Not all side effects reported for JARDIANCE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking JARDIANCE, please consult your healthcare provider for advice.

Some symptoms need immediate medical attention. Stop taking JARDIANCE and see a doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following serious or potentially serious side effects:

- any sign of an allergic reaction (hypersensitivity) such as skin rash, hives, and swelling of the face, lips, tongue and throat that may cause difficulty in breathing or swallowing and wheezing and shortness of breath.
- any sign of ketoacidosis, such as
 - increased levels of 'ketone bodies' in your urine or blood
 - feeling sick or being sick
 - rapid weight loss
 - stomach pain
 - excessive thirst
 - fast and deep breathing
 - confusion
 - unusual sleepiness or tiredness
 - a sweet smell to your breath, a sweet or metallic taste in your mouth or a different odour to your urine or sweat.

This may occur regardless of your blood glucose (sugar) level. Your doctor may decide to stop your treatment with JARDIANCE temporarily or permanently. Please see also section 2 'Warnings and precautions'.

These are all very serious side effects. If you have them, you may have had a serious reaction to JARDIANCE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if you experience pain or tenderness, itching, swelling in the genital or back passage area, fever or are generally feeling unwell.

These may be symptoms of a serious and life threatening infection called Fournier's gangrene seen less frequently. Your doctor may tell you to stop taking JARDIANCE. Please see also section 2 'Warnings and precautions'.

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

- *Low blood sugar (hypoglycaemia)*, seen frequently when taking JARDIANCE with another medicine for treatment of type 2 diabetes, called a sulphonylurea or with insulin.

The signs of low blood sugar may include:

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

Talk to your doctor or other healthcare professional about how to recognise, manage and prevent low blood sugar (hypoglycaemia). If you have symptoms of low blood sugar, eat a high sugar snack or drink juice or soda which contains sugar. Measure your blood sugar if possible and rest.

- *Urinary tract infection*, seen frequently:
The signs of urinary tract infection are:
 - burning sensation when passing urine
 - urine that appears cloudy
 - pain in the pelvis, or mid-back pain, sometimes with fever, nausea or vomiting (when the kidneys are infected).
 The signs of an urge to pass urine or more frequent urination may occur frequently and can be due to the way JARDIANCE works, however as they can also be signs of a urinary tract infection, you should contact your doctor if you note an increase in such symptoms.
Serious urinary tract infections that can lead to hospitalisation may occur.
- *Dehydration* (excessive loss of fluid from your body) seen frequently. The signs of dehydration are not specific, however, may include:
 - unusual thirst
 - light-headedness or dizziness upon standing
 - fainting or loss of consciousness.

Some people have had the following side effects while taking JARDIANCE:

Frequent:

- genital infection and genital yeast infection (especially in women)
- itching
- constipation
- passing more urine than usual or needing to pass urine more often
- thirst
- increased blood fats (lipids)
- sugar (glucose) in the urine
- weight loss.

Less frequent:

- 'ketones' in the urine
- straining or pain when emptying the bladder
- increase in test results for:
 - blood creatinine (a chemical waste molecule which is generated from your metabolism process)
 - volume of red blood cells in your blood (haematocrit)
 - decrease in kidney filtration rate.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to the South African Health Products Regulatory Authority (SAHPRA) via the Med Safety App (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Suspected adverse reactions can also be reported directly to the holder of the certificate of registration using the email address pv_local_south_africa@boehringer-ingenheim.com. By reporting side effects, you can help provide more information on the safety of JARDIANCE.

5. How to store JARDIANCE

Store at or below 30 °C.

Store all medicines out of reach of children.

Do not use JARDIANCE after the expiry date which is stated on the blister and the carton.

The expiry date refers to the last day of that month.

Do not use JARDIANCE if the package is damaged or shows signs of tampering.

Return all unused or expired medicines to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What JARDIANCE contains

- The active substance is empagliflozin. Each film-coated tablet contains 10 mg or 25 mg empagliflozin.
- The other ingredients are:
 - colloidal anhydrous silica
 - croscarmellose sodium
 - hydroxypropylcellulose
 - hypromellose
 - iron oxide yellow
 - lactose monohydrate
 - macrogol
 - magnesium stearate
 - microcrystalline cellulose
 - talc
 - titanium dioxide.

The tablets contain 162,5 mg lactose monohydrate per JARDIANCE 10 mg tablet and 113 mg lactose monohydrate per JARDIANCE 25 mg tablet.

What JARDIANCE looks like and contents of the pack

JARDIANCE 10 mg: Pale yellow, round, biconvex, bevel-edged film-coated tablets debossed on one side with the Boehringer Ingelheim company symbol and 'S10' on the other side.

JARDIANCE 25 mg: Pale yellow, oval, biconvex, film-coated tablets debossed on one side with the Boehringer Ingelheim company symbol and 'S25' on the other side.

JARDIANCE 10 mg and 25 mg film-coated tablets are packed in blister strips, consisting of colourless, transparent plastic foil and printed aluminium foil. The blister strips are packed in printed cardboard cartons in packs of 30 tablets (3 blister strips of 10 tablets each).

Holder of Certificate of Registration

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