

APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET _____

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

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



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.

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 taking JARDIANCE, which is life threatening and needs to be treated in hospital.
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 'Take special care with JARDIANCE'.

1. WHAT JARDIANCE FILM-COATED TABLETS CONTAIN

- The active substance of this medicine is empagliflozin. Each film-coated tablet contains 10 mg or 25 mg empagliflozin.
- The other (inactive) 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 per JARDIANCE 10 mg tablet and 113 mg lactose per JARDIANCE 25 mg tablet.

2. WHAT JARDIANCE FILM-COATED TABLETS ARE USED FOR

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 is also used in adults with 'type 2 diabetes' if you have 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.

JARDIANCE must not be used if you have severe kidney problems.

JARDIANCE is a medicine which is taken by mouth to treat high blood sugar levels. The active ingredient in JARDIANCE, empagliflozin, works by blocking a protein in the kidneys called sodium glucose cotransporter 2 (SGLT2).

JARDIANCE is not to be used in people with 'type 1 diabetes'.

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 insulin given by injection.

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.

It is important to follow the advice about diet and exercise that you have been given by your healthcare provider.

3. BEFORE YOU TAKE JARDIANCE FILM-COATED TABLETS

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 1).
- if you have type 1 diabetes.
- if you have increased levels of ketone bodies in your urine or blood (see **Take special care with JARDIANCE**).
- if you have severe kidney problems, or have kidney failure and are on renal dialysis.
- if you are pregnant or if you are breast feeding 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.

Take special care with JARDIANCE:

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

- experience any of the following symptoms (even if your blood sugar levels are normal): feeling sick or being sick, loss of appetite, 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 with diabetes because of increased levels of 'ketone bodies' in your urine or blood. 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 taking JARDIANCE, regardless of blood sugar level. Stop taking JARDIANCE and contact a doctor or the nearest hospital immediately.

- are taking or using any other medicines 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 in section 5: **POSSIBLE SIDE EFFECTS** and **Driving and using machinery**.
- have serious kidney problems your doctor may ask you to take a different medicine (see **WHAT JARDIANCE FILM-COATED TABLETS ARE USED FOR**). Your kidney function should be assessed before you start taking JARDIANCE, at least 6 monthly during treatment, and if you are taking JARDIANCE together with metformin, another medicine used to control your 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 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 5: **POSSIBLE SIDE EFFECTS**.
- 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.
- are 85 years old or older, you should not start taking JARDIANCE.

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 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.

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

Taking JARDIANCE with food and drink:

You can take JARDIANCE with or without food.

Pregnancy and breast feeding:

You must not take JARDIANCE if you are pregnant.

Talk to your healthcare provider before you take JARDIANCE if you plan to become pregnant.

Do not take JARDIANCE if you are breast feeding.

If you are pregnant, or breast feeding your baby, please consult your healthcare provider for advice before you start taking JARDIANCE.

Driving and using machinery:

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

Taking JARDIANCE in combination with medicines called sulphonylureas 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 jitteriness, 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.

Important information about some of the ingredients of JARDIANCE:

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

Taking other medicines with JARDIANCE:

Always tell your healthcare provider if you are taking any other medicine (this includes 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).
- if you are taking a medicine used to remove water from the body (diuretics sometimes called 'water tablets'). Your doctor may ask you to stop taking JARDIANCE. Possible signs of losing excessive fluids from your body are listed in section 5: **POSSIBLE SIDE EFFECTS**.

4. HOW TO TAKE JARDIANCE FILM-COATED TABLETS

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

Follow your healthcare provider's directions carefully.

Always take JARDIANCE film-coated tablets every day exactly as your doctor told you.

Do not take more or less tablets and do not take them more often than recommended.

You should check with your healthcare provider if you are not sure.

The recommended starting dosage of JARDIANCE is one 10 mg tablet once a day. Your doctor will decide whether to increase the dose to 25 mg once a day if your blood glucose is not adequately controlled with a dose of 10 mg per day. Your doctor will prescribe the strength that is right for you. Do not change your dose unless your doctor has told you to.

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 each day. This will help you to remember to take it.

Continue to take JARDIANCE as long as your doctor prescribes it so you can continue to help control your blood sugar. 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.

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.

Check your blood sugar as your healthcare professional tells you to. 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 control 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.

Effects when treatment with JARDIANCE is stopped:

Do not stop taking JARDIANCE without first consulting your doctor. 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.

5. 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 as soon as possible 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
 - loss of appetite
 - 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 temporarily or permanently stop your treatment with JARDIANCE. Please see also the section **Take special care with JARDIANCE**.

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. Your doctor may tell you to stop taking JARDIANCE. Please see also the section **Take special care with JARDIANCE**.

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

- *Low blood sugar (hypoglycaemia)*, seen frequently when taking JARDIANCE with a sulphonylurea or with insulin.

The signs of low blood sugar may include:

- jitteriness, sweating, feeling very anxious or confused, fast heart beat
- 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 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 less 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:

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

Less frequent:

- straining or pain when emptying the bladder
- 'ketones' in the urine
- 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.

6. STORING AND DISPOSING OF JARDIANCE FILM-COATED TABLETS

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

7. PRESENTATION OF JARDIANCE FILM-COATED TABLETS

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).

8. IDENTIFICATION OF JARDIANCE FILM-COATED TABLETS

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.

9. REGISTRATION NUMBER

JARDIANCE 10 mg: 48/21.2/1380

JARDIANCE 25 mg: 48/21.2/0411

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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