

For Ireland please report adverse events to the HPRA, online or by post. HPRA link for on-line reporting, or download a form: https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form. Adverse events can also be reported to Boehringer Ingelheim Drug Safety on 01 291 3960

You have received this leaflet because you've been prescribed Jardiance for the treatment of Type 2 Diabetes.





What is Type 2 Diabetes?

Type 2 Diabetes is a condition in which your body does not make enough insulin to control the level of glucose (sugar) in your blood or when your body can't use insulin effectively. This causes high levels of glucose in your blood, which can lead to Cardiovascular health problems like heart disease as well as kidney disease, nerve and eye problems.¹

What is Jardiance (empagliflozin) and what is it used for?

Jardiance is a medicine for treating Type 2 Diabetes. It helps to control your blood glucose (sugar) levels and can also help to reduce your weight and blood pressure. It can also reduce your risk of Cardiovascular complications if you have Type 2 Diabetes and Cardiovascular Disease.

The active ingredient in Jardiance is called empagliflozin. You will also see this name on the box.

Jardiance works by blocking the reabsorption of glucose into the body via the kidney, so this excess glucose is removed in the urine

How do I take Jardiance (empagliflozin)?

Jardiance is a medicine for treating Type 2 Diabetes. It helps to control your blood glucose (sugar) levels.¹ When you first start taking Jardiance take one 10mg tablet once a day. Depending on how well this works, your doctor may increase the amount you take to one 25mg tablet once a day. ¹

You can take your tablet at **any time of the day**. You can take it when you have a meal or **something to eat**, or you can take it on its own **without food**. Whatever time you choose, make it the same every day to help you remember to take it.¹

Swallow the tablet whole with some water.1

If you are not sure whether you're taking Jardiance in the right way, talk to your doctor, nurse or pharmacist.¹

Jardiance can be used on its own for patients who cannot take metformin. Jardiance can also be used with other glucose-lowering medicine(s). These may be medicine(s) taken by mouth or given as an injection, for example, insulin.



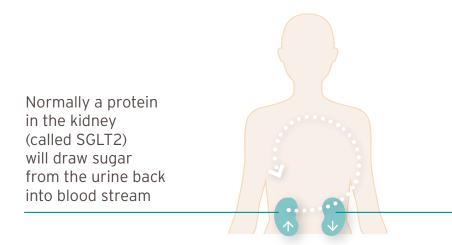
Please note

While you're taking Jardiance, it is important to keep going with your diet and exercise plan as advised by your doctor, pharmacist or nurse.¹

How does Jardiance (empagliflozin) work?

In diabetes, blood sugar levels are high and excess sugar is lost from the body via the urine. A protein in the kidneys (SGLT2) draws sugar back into the blood from the urine. Jardiance works by blocking this protein (SGLT2) in your kidneys, and this causes glucose to be removed from your body via your urine. This means that when you pass urine you will get rid of some of the excess glucose in your body.¹

Because of how this medicine works, there will be sugar in your urine when it is tested. This is expected when you take this medicine.¹



Jardiance blocks the SGLT2 protein and the sugar (glucose) is excreted in the urine instead

Can I take Jardiance (empagliflozin) with other medicines?

Yes, you can take Jardiance with other medicines. Tell your doctor about any other medicines you're taking or have taken.¹

It is particularly important to tell your doctor:

- If you're taking a medicine to remove excess water from your body (sometimes called water tablets or diuretics). Taking this type of medicine together with Jardiance can cause you to lose too much water (dehydration).
 If you become dehydrated you might feel thirsty, light-headed or dizzy when you stand up. If you have severe dehydration you might faint or become unconscious.¹
- If you're taking other medicines that lower your blood glucose levels, such as other medicines to treat diabetes.¹ Your doctor may give you a smaller amount of these other medicines to prevent your blood sugar levels from getting too low.¹

When should I not be taking Jardiance (empagliflozin)?



If you're aged 85 or over you shouldn't take Jardiance at all. If you're aged 75 and over there may be a higher likelihood that you may become dehydrated whilst taking Jardiance. Talk to your doctor about this, and how you can prevent it from happening.¹

If you're being sick, have diarrhoea, or a fever, or if you're not able to eat or drink, discuss this with your doctor since they may ask you to stop taking Jardiance until you are better. This is to prevent you losing too much fluid and becoming dehydrated.¹

If you have a serious kidney infection or urinary tract infection and have a fever, your doctor may ask you to stop taking Jardiance until you have recovered. The information leaflet in your medicine pack has more information about how to take Jardiance safely.¹

Can I take Jardiance (empagliflozin) if I am pregnant or breast feeding?

No. If you're pregnant or breast feeding you shouldn't take Jardiance. If you think you might be pregnant or are planning to have a baby, talk to your doctor.¹

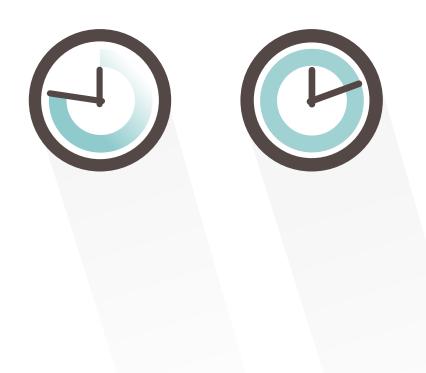
What should I do if I take more Jardiance (empagliflozin) than I should?

If you take more Jardiance than you should seek medical advice immediately. Take the medicine pack with you.¹

What should I do if I forget to take Jardiance (empagliflozin)?

What to do, if you forget to take a tablet, depends on how long it is until you are due to take your next tablet.¹

- If it is **12 hours or more** until the time you would be due to take your next tablet, take Jardiance as soon as you remember. Then take your next dose at the usual time.¹
- If it is less than 12 hours until the time you would be due to take your next tablet, don't take the missed tablet. Take your next tablet at the usual time.¹
- DO NOT take a double dose of Jardiance to make up for a forgotten dose.¹
- **DO NOT** stop taking Jardiance without talking to your doctor. If you stop taking Jardiance, your blood glucose levels may go up.¹



What are the possible side effects of Jardiance (empagliflozin), and what should I do about them?

If you take Jardiance with another medicine that can cause low blood sugar, such as a sulphonylurea (such as glimepiride, gliclazide or glipizide) or insulin, your risk of getting low blood sugar is higher.



The signs of low blood sugar (hypoglycaemia) may include:

Shaking sweating very anxious confused FAST HEART BEAT excessive hunger headache

Your doctor will tell you how to treat low blood sugar levels and what to do if you get any of the signs above. If you have symptoms of low blood sugar, eat glucose tablets, a high sugar snack or drink fruit juice. Measure your blood sugar if possible and rest.¹

Other common side effects of Jardiance are:



Uncommon side effects of Jardiance include:

- Pain when you're passing urine
- Dehydration¹
- Hives

What are the signs of a urinary tract infection and what should I do if I get an infection?

The symptoms of a urinary tract infection are a burning sensation when you pass urine, pain in your pelvis or mid back pain. Your urine may also look cloudy and smell offensive. An urge to pass urine more often than usual can be caused by the way Jardiance works, but it can also be a sign of an infection. If you start passing urine more often, talk to your doctor.¹

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 couldbe a sign of a rare but serious infection that has to be treated straight away.

Diabetic ketoacidosis

Diabetic ketoacidosis is a rare, but serious, sometimes life-threatening condition in diabetes affecting up to 1 in 1,000 people.

These are the symptoms:

- Rapid weight loss
- Feeling sick or being sick
- Stomach pain
- Excessive thirst
- Fast and deep breathing
- Confusion
- Unusual sleepiness or tiredness

Contact a doctor or the nearest hospital straight away if you have any of these symptoms. Your doctor may decide to temporarily or permanently stop your treatment with Jardiance (empagliflozin).

• 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 blood glucose level.

Reporting side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

UK

You can also report side effects directly via the Yellow Card Scheme at <u>www.mhra.gov.uk/yellowcard</u> By reporting side effects you can help provide more information on the safety of this medicine.

Adverse events can also be reported to: Boehringer Ingelheim Drug Safety on 0800 328 1627.

IRELAND

Please report adverse events to the HPRA, online or by post.HPRA link for on-line reporting, or download a form: **www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form.**

Adverse events can also be reported to Boehringer Ingelheim Drug Safety on 01 291 3960

Foot care

Having Type 2 Diabetes increases your risk of infection and sores on your feet. While taking Jardiance, it is particularly important that you check your feet regularly and follow your doctor's advice on routine preventative foot care and adequate hydration.

Tell your doctor about any:

- Wounds
- Discolouration
- Foot tenderness
- Foot pain

It is important that you speak to your doctor about any questions or concerns you have about your treatment.

Is there anything else I need to know?

Jardiance has lactose in it. If you're intolerant to lactose talk to your doctor. Before starting this treatment, it is important to keep going with your diet and exercise plan.¹

There is more information about Jardiance in the information sheet that comes with your medicines. If you have questions about taking it, speak to your doctor or pharmacist.¹





Helpful information

We hope that this booklet has helped to answer the questions you have. You can talk to your nurse about anything that's worrying you about your treatment. We've also included some links to a variety of websites that may also offer further information.

UK:

https://www.diabetes.org.uk/ https://www.nhs.uk/Conditions/Diabetes/Pages/Diabetes.aspx https://www.diabetes.co.uk/

Ireland: www.diabetes.ie

Glossary

Class

a group of drugs that have certain things in common and work in a similar way.

Dehydration

dryness resulting from the removal of fluids in the body when your body loses more fluid than you can take in.

Diuretic

a drug or substance that causes excess production of urine.

Glucose

the main type of sugar in the blood.

Hypoglycaemia

low blood sugar levels.

Insulin

a hormone made by the pancreas. Changes in insulin help keep your blood sugar level from getting too high or too low.

Metformin

a glucose lowering drug commonly prescribed to treat Type 2 Diabetes.

SGLT2

an abbreviation for sodium glucose co-transporter 2, a protein in the kidney which brings sugar back into the bloodstream from the urine.

Sulphonylureas

a group of glucose lowering drugs that are commonly used in the management of Type 2 Diabetes.

Thrush

a yeast infection in the genital area.

Urinary tract infection usually an infection in the bladder.

Urination

the release of urine from the bladder.

Yellow card scheme

used to collect information from both health professionals and the general public on suspected side effects. It allows patients to report side effects directly by going to **www.mhra.gov.uk/yellowcard**

Name:
Doctor:
Surgery Address:
Diabetes Nurse:
Telephone:
Email:
Hospital/Clinic telephone number:

These pages may be useful for you to keep a note of information about your medication and your diabetes.

Notes			

Date I started Jardiance (empagliflozin)

Date for next prescription

It may be helpful to record your **HbA1c and weight readings** to discuss with your doctor

Date	HbA1c	Date	Weight

If you have any feedback on this piece of information please contact **communications.bra@boehringer-ingelheim.com**



