

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

Jardiance®

Frequently asked questions and answers

What are the
signs of low
blood sugar?

Are there any
side effects?

What is Type 2
Diabetes?



Before starting your treatment, carefully
read the patient information leaflet
included in your medication pack.

Great Britain: please report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events can also be reported to: Boehringer Ingelheim Drug Safety on 0800 328 1627.

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.



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

Jardiance is a medicine for treating type 2 diabetes. It helps control your blood glucose (sugar) levels and can also help to reduce your weight and blood pressure. It can also help prevent heart disease and reduce your risk of cardiovascular complications if you have type 2 diabetes and cardiovascular disease.

Jardiance works by blocking the reabsorption of glucose into the body via the kidney, so that excess glucose is removed in the urine. This lowers the amount of sugar in your blood.

How do I take Jardiance (empagliflozin)?

Jardiance is a medicine for treating Type 2 Diabetes. It helps to control your blood glucose (sugar) levels. 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.

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.

Swallow the tablet whole with some water.

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

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.



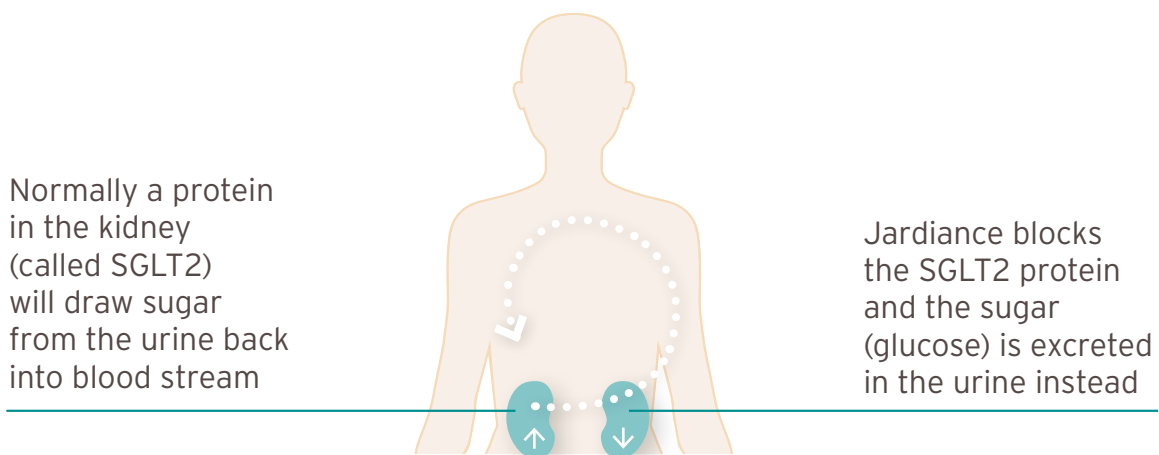
Please note

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.

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.

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.



Can I take Jardiance (empagliflozin) with other medicines?

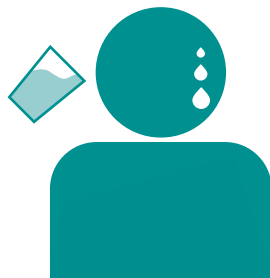
Yes, you can take Jardiance with other medicines. Tell your doctor about any other medicines you're taking or have taken.

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.
- If you're taking other medicines that lower your blood glucose levels, such as other medicines to treat diabetes. Your doctor may give you a lower dose of these other medicines to prevent your blood sugar levels from getting too low.
- If you are taking lithium because Jardiance can lower the amount of lithium in your blood.

When should I not be taking Jardiance (empagliflozin)?

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.



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.

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.

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.

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.

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.

- 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.
- 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.
- **DO NOT** take a double dose of Jardiance to make up for a forgotten dose.
- **DO NOT** stop taking Jardiance without talking to your doctor.
If you stop taking Jardiance, your blood glucose levels may go up.



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

Contact your doctor as soon as possible if you notice any of the following side effects.

Low blood sugar (hypoglycaemia)

If you take Jardiance with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin, your risk of getting low blood sugar is higher.



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.

Dehydration

Ask your doctor about ways to prevent dehydration. If you are dehydrated, your doctor may ask you to stop taking Jardiance until you recover to prevent loss of too much body fluid.

Unusual thirst
Lightheadedness
Dizziness upon standing
Fainting
Loss of consciousness

Burning sensation
Cloudy Urine

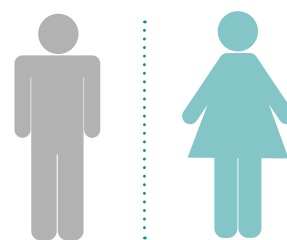
Pelvis or mid-back pain

Urinary tract infection

An urge to pass urine or more frequent urination may be due to the way Jardiance works, but they can also be signs of urinary tract infection. If you note an increase in such symptoms, you should also contact your doctor.

Genital yeast infection (thrush)

This common side effect may affect up to 1 in 10 people. As this medicine increases the glucose in your urine, there is an increased risk of genital infection such as thrush. Consult your doctor or pharmacist for treatment and advice if irritation or itching occurs in this area.



Other common side effects include:

- Itching
- Rash or red skin - this may be itchy and include raised bumps, oozing fluid or blisters
- Blood tests may show an increase in blood fat (cholesterol) levels in your blood
- Passing more urine than usual or needing to pass urine more often
- Thirst
- Constipation

Uncommon side effects include:

- Hives
- Straining or pain when emptying the bladder
- Blood tests may show a decrease in kidney function (creatinine or urea)
- Blood tests may show increases in the amount of red blood cells in your blood (haematocrit)
- Ketoacidosis

Ketoacidosis

Ketoacidosis is an uncommon, but serious, sometimes life-threatening problem you can get with diabetes or when taking Jardiance, affecting up to 1 in 100 people.

These are the symptoms

- Increased levels of “ketone bodies” in your urine or blood
- 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.

Contact a doctor or the nearest hospital straight away.

Your doctor may decide to temporarily or permanently stop your treatment with Jardiance (empagliflozin).

This may occur regardless of blood glucose level. The risk of developing ketoacidosis may be increased with prolonged fasting, excessive alcohol consumption, dehydration, sudden reductions in insulin dose, or a higher need of insulin due to major surgery or serious illness.

Contact a doctor or the nearest hospital straight away if you have a severe allergic reaction (seen in up to 1 in 100 people).

Possible signs may include swelling of the face, lips, mouth, tongue, or throat that may lead to difficulty breathing or swallowing.

Rare side effects include:

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

Necrotising fasciitis

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 infection that has to be treated straight away.

Very rare side effects include:

- Inflammation of the kidneys (tubulointerstitial nephritis)

Tubulointerstitial nephritis

Tubulointerstitial nephritis is a very rare inflammation that affects the tubules of the kidneys and the tissues that surround them. People may have excessive urination, urinate at night, or have fever and/or a rash.

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.

Great Britain

You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard 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.**

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.



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

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



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.

www.diabetes.org.uk
www.nhs.uk/conditions/type-2-diabetes
www.diabetes.co.uk

Glossary

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.

Hives

raised, itchy, red rash.

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:

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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

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Date I started Jardiance (empagliflozin)

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Date for next prescription

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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