

# Jardiance®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using Jardiance?

Jardiance tablets contain the active ingredient empagliflozin. Jardiance is used to lower blood sugar levels in people with type 2 diabetes mellitus. Jardiance can be used to help lower the risk of dying from cardiovascular disease in patients with type 2 diabetes mellitus and cardiovascular disease. Jardiance is also used to treat a type of long-term heart failure in patients with or without type 2 diabetes mellitus. For more information, see Section [1. Why am I using Jardiance?](#) in the full CMI.

### 2. What should I know before I use Jardiance?

Do not use if you have ever had an allergic reaction to empagliflozin or any of the ingredients listed at the end of the CMI.

Do not use if you have poorly functioning kidneys since Jardiance requires good functioning kidneys to work well.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use Jardiance?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Jardiance and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use Jardiance?**

Your doctor will tell you how many tablets you need to take each day. The usual dose for adults is one tablet a day. More instructions can be found in Section [4. How do I use Jardiance?](#) in the full CMI.

### **5. What should I know while using Jardiance?**

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>• Check your blood sugar levels regularly to tell if</li></ul>

	<p>your diabetes is being controlled properly</p> <ul style="list-style-type: none"> <li>● Be careful when doing activities that can lower your sugar levels, such as drinking alcohol, not eating enough, or exercising suddenly or vigorously.</li> <li>● Remind any doctor, dentist or pharmacist you visit that you are using Jardiance.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>● Do not stop taking your medicine or change the dosage without checking with your doctor</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>● Be careful before you drive or use any machines or tools until you know how Jardiance affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>● Drinking alcohol can increase the risk of your blood sugar levels becoming too low. Talk to your doctor if you drink alcohol.</li> </ul>

### Looking after your medicine

- Keep your tablets in the pack until it is time to take it.
- Store it in a cool, dry place where the temperature stays below 30°C.

For more information, see Section [5. What should I know while using Jardiance?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include: genital burning, redness, pain, discharge; passing more urine than normal; thirst; itchiness; and constipation. Serious potential side effects that may require medical attention include: low blood sugar (when used in combination with other anti-diabetic medicines); dehydration; burning sensation when passing urine; cloudy urine; straining or pain when passing urine; and pain the pelvis or mid-back. Side effects that require urgent medical attention include swelling of the penis; Fournier's gangrene; allergic reactions; and ketoacidosis. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# Jardiance®

**Active ingredient:** *empagliflozin*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using Jardiance. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Jardiance.**

**Where to find information in this leaflet:**

- [1. Why am I using Jardiance?](#)
- [2. What should I know before I use Jardiance?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Jardiance?](#)
- [5. What should I know while using Jardiance?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using Jardiance?

**Jardiance contains the active ingredient empagliflozin.**

It belongs to a group of medicines called sodium-glucose co-transporter 2 (SGLT2) inhibitors. It works by blocking a protein in the kidneys called SGLT2 and removes blood sugar via the urine. As a result, the levels of sugar

in your blood are reduced. Jardiance also reduces the amount of salt reabsorbed by your kidneys, which helps to reduce excess strain on the heart.

## **Type 2 diabetes mellitus**

**Jardiance is a medicine used to lower blood sugar levels in patients with type 2 diabetes mellitus when diet and exercise is not enough to control your blood sugar levels.**

Type 2 diabetes mellitus (also known as non-insulin-dependent diabetes mellitus) develops when your body doesn't make enough insulin or the insulin your body makes does not work as well as it should. Insulin helps to control your blood sugar levels, and when there is not enough insulin or it does not work well, the amount of sugar in your blood can start to build up. Too much sugar in the blood can cause damage to the body's cells, and can lead to problems with your eyes, heart, kidneys, and circulation.

Jardiance may be used when diet plus exercise do not provide adequate blood sugar level control either:

- alone as a single medicine, or
- in combination with other anti-diabetic medicines such as:
  - metformin
  - sulfonylurea medicines such as glimepiride and glibenclamide
  - pioglitazone

- insulin
- dipeptidyl peptidase-4 inhibitor medicines such as linagliptin or sitagliptin.

**If you have type 2 diabetes mellitus and cardiovascular disease, Jardiance can also be used to reduce your risk of dying from your cardiovascular disease.**

## **Heart Failure**

Jardiance is also used with other medicines to treat a type of long-term heart failure in patients with or without type 2 diabetes mellitus

In heart failure, the heart does not work as well as it should. This means the heart is unable to pump enough blood to meet the body's needs. The most common symptoms of heart failure are breathlessness, fatigue, tiredness and ankle swelling.

## **2. What should I know before I use Jardiance?**

### **Warnings**

#### **Do not use Jardiance if:**

- you are allergic to empagliflozin, or any of the ingredients listed at the end of this leaflet
- you have poorly functioning kidneys since Jardiance requires good functioning kidneys to work well.

## **Tell your doctor if you:**

- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives, or dyes.
- have or have had any of the following medical conditions:
  - type 1 diabetes mellitus, a condition where your body does not produce insulin
  - ketoacidosis, a condition where acids called “ketones” build up to a dangerous level in the blood, which can lead to severe complications including pre coma in patients with type 2 diabetes mellitus.
  - kidney problems
  - galactosaemia, a rare hereditary condition of galactose intolerance
  - frequent genital or urinary tract infections (infections of the bladder, kidney, or tubes that carry urine)
  - illnesses that can cause dehydration (e.g. diarrhoea or a severe infection)
  - increased urine loss which may affect the fluid balance in your body and increase your risk of dehydration.
  - if you have heart problems, a history of low blood pressure or are 75 years of age or older, your risk of dehydration might be increased.
- are over 85 years of age.

You should not start taking Jardiance if you are over 85 years of age.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

**Do not take Jardiance if you are pregnant.**

It may affect your developing baby if you take it during pregnancy.

**Do not breastfeed if you are taking Jardiance.**

It is not known if the active ingredient in Jardiance passes into human breast milk and there is a possibility that your baby may be affected.

## **Children**

- Do not give this medicine to a child under the age of 18 years.

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Jardiance can increase the effects of diuretic medicines (water pills) which are used to treat blood pressure and fluid retention. Taking these medicines together can increase your risk of low blood pressure and dehydration.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Jardiance.**

## **4. How do I use Jardiance?**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet

### **How much to take**

#### **Type 2 diabetes mellitus**

The recommended dose is one 10 mg tablet once a day.

Your doctor may increase your dose to one 25 mg tablet once a day if your blood sugar levels remain high after starting treatment on 10 mg.

Your doctor will prescribe Jardiance alone or in combination with another anti-diabetic medicine if that medicine alone is not sufficient to control your blood sugar level.

## **Heart Failure**

The recommended dose is one 10 mg tablet once a day.

**Continue taking your medicine for as long as your doctor tells you.**

## **When to take Jardiance**

Take Jardiance at the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take Jardiance before or after food.

## **How to take Jardiance**

Swallow the tablet whole with a full glass of water.

## **If you forget to take Jardiance**

**If you miss your dose at the usual time, and it is almost time for your next dose (less than 12 hours), skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

**Do not take a double dose to make up for the dose you missed.** This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

## **If you use too much Jardiance**

If you think that you have taken too much Jardiance, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using Jardiance?**

### **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are using Jardiance, especially if you are about to start any new medicine or if you are going to have surgery.
- Tell your doctor immediately if you become pregnant while taking Jardiance.
- If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

- Keep all of your doctor's appointments so that your progress can be checked.
- Follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise.
- Check your blood sugar levels regularly. This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.
- Check your feet regularly and see your doctor if you notice any problems. Follow any other advice regarding foot care given by your doctor.
- Talk to you doctor if you are about to have surgery. The doctor will provide instructions on when to stop and restart Jardiance.

## **Things you should not do**

- Do not take Jardiance to treat any other conditions unless your doctor tells you to.
- Do not give your medicine to anyone else even if they have the same condition as you.
- Do not stop taking this medicine or change the dosage without checking with your doctor.

## **Things to be careful of**

Be careful when doing any of the following things, which may increase the risk of your blood sugar becoming too low:

- Drinking alcohol
- Not eating enough

- Doing unexpected or vigorous exercise

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how Jardiance affects you.**

When Jardiance is taken with other anti-diabetic medicines, such as sulfonylurea or insulin, it can increase the risk of your blood sugar levels becoming too low. Low blood sugar can cause dizziness, lightheadedness, tiredness, drowsiness, and slow your reaction time, which can affect your ability to drive or operate machinery.

If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Alcohol may increase the risk of your blood sugar levels becoming too low.

## **Looking after your medicine**

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they may not keep well.
- Keep your Jardiance tablets in a cool dry place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where children cannot reach it.**

## **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

## Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>● <b>Symptoms of a genital yeast infection</b></li><li>● genital burning, redness, pain or discharge</li></ul> <p><b>Other less serious side effects</b></p> <ul style="list-style-type: none"><li>● passing more urine than normal</li><li>● itching</li><li>● thirst</li><li>● constipation</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

## Serious side effects

Serious side effects	What to do
<p><b>Symptoms of low blood sugar</b></p> <ul style="list-style-type: none"><li>● sweating</li><li>● weakness</li><li>● hunger</li><li>● dizziness</li><li>● trembling</li><li>● headache</li></ul>	<p><b>Speak to your doctor as soon as possible if you have any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● confusion</li> <li>● flushing or paleness</li> <li>● numbness</li> <li>● fast, pounding heartbeat</li> </ul> <p>Low blood sugar may occur in patients who already take another medication to treat diabetes, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be reduced while taking Jardiance.</p> <p><b>Symptoms of dehydration</b></p> <ul style="list-style-type: none"> <li>● dry or sticky mouth</li> <li>● unusual thirst</li> <li>● light-headedness or dizziness upon standing</li> <li>● fainting or loss of consciousness</li> <li>● urinating less often than normal or not at all</li> </ul> <p>There is an increased risk of dehydration (loss of needed fluids from your body; volume depletion)</p>	

<b>Serious side effects</b>	<b>What to do</b>
<p>in patients who have diarrhoea or fever, are unable to eat or drink, aged 75 years or older or taking medicines to lower blood pressure.</p> <p><b>Symptoms of a urinary tract infection</b></p> <ul style="list-style-type: none"> <li>● burning sensation when passing urine</li> <li>● urine that appears cloudy</li> <li>● pain in the pelvis or mid-back</li> <li>● straining or pain when passing urine</li> </ul>	

### **Very serious side effects**

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Genital</b></p> <ul style="list-style-type: none"> <li>● Swelling of the penis that makes it difficult to pull back the skin around the tip of the penis (uncircumcised men)</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects</b></p>

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Symptoms of Fournier's gangrene</b></p> <ul style="list-style-type: none"> <li>● pain, tenderness, itching, or swelling in the genital or back passage area</li> <li>● fever</li> <li>● generally feeling unwell</li> </ul> <p><b>Symptoms of an allergic reaction</b></p> <ul style="list-style-type: none"> <li>● swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing</li> <li>● severe and sudden onset of itchy or raised skin rash, hives, or nettle rash</li> </ul> <p><b>Symptoms of ketoacidosis</b></p> <ul style="list-style-type: none"> <li>● rapid weight loss</li> <li>● feeling sick or being sick</li> <li>● stomach pain</li> <li>● excessive thirst</li> <li>● fast and deep breathing</li> <li>● confusion</li> </ul>	

<b>Very serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● unusual sleepiness or tiredness</li> <li>● sweet smell to your breath</li> <li>● sweet or metallic taste in your mouth</li> <li>● different odour to your urine or sweat</li> </ul> <p>In rare cases, empagliflozin, the active substance in Jardiance, can cause a serious side effect called ketoacidosis.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What Jardiance contains**

<b>Active ingredient (main ingredient)</b>	<ul style="list-style-type: none"><li>● empagliflozin 10 mg</li><li>● empagliflozin 25 mg</li></ul>
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>● lactose monohydrate</li><li>● microcrystalline cellulose</li><li>● hypromellose</li><li>● croscarmellose sodium</li><li>● colloidal anhydrous silica</li><li>● magnesium stearate.</li></ul> <p>Tablet coating:</p> <ul style="list-style-type: none"><li>● hypromellose</li><li>● titanium dioxide</li><li>● purified talc</li><li>● macrogol 400</li></ul>

	<ul style="list-style-type: none"> <li>• iron oxide yellow.</li> </ul>
<b>Potential allergens</b>	lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What Jardiance looks like**

Jardiance is available in two strengths:

Jardiance 10 mg tablets (AUST R 208829) are pale yellow, round, biconvex and bevel-edged, marked with the BI company logo on one side and 'S10' on the other side.

Jardiance 25 mg tablets (AUST R 208827) are pale yellow, oval and biconvex, marked with the BI company logo on one side and 'S25' on the other side.

Jardiance tablets are available in PVC/Aluminium blister packs of 10 (sample) or 30 tablets.

## **Who distributes Jardiance**

Jardiance tablets are supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney NSW

[www.boehringer-ingelheim.com.au](http://www.boehringer-ingelheim.com.au)

This leaflet was prepared in June 2022.

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