

Jardiamet®

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.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using Jardiamet?

Jardiamet contains the active ingredient empagliflozin and metformin. Jardiamet is used to lower blood sugar levels in patients (adults and children aged 10 years and older) with type 2 diabetes mellitus. It 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 certain other anti-diabetic medicines.

For more information, see Section [1. Why am I using Jardiamet?](#) in the full CMI.

2. What should I know before I use Jardiamet?

Do not use if you have ever had an allergic reaction to empagliflozin or metformin or any of the ingredients listed at the end of the CMI. Do not give this medicine to a child under the age of 10 years. **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 Jardiamet?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Jardiamet 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 Jardiamet?

Your doctor will tell you how many tablets you need to take each day. The usual dose for adults and children aged 10 years and above is one tablet twice a day.

More instructions can be found in Section [4. How do I use Jardiamet?](#) in the full CMI.

5. What should I know while using Jardiamet?

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

	your blood sugar levels becoming too low. Talk to your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none"> • 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 Jardiamet?](#) 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; loss in appetite, loss of taste, diarrhoea, stomach ache, feeling sick, vomiting, 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 in 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.

- ▼ Use of this medicinal product in paediatric patients aged 10 to 17 years with type 2 diabetes mellitus is subject to additional monitoring in Australia. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse events at www.tga.gov.au/reporting-problems.

Jardiamet

Active ingredient(s): empagliflozin and metformin hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Jardiamet. **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 Jardiamet.**

Where to find information in this leaflet:

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

1. Why am I using Jardiamet?

Jardiamet contains the active ingredient empagliflozin (which belongs to a group of medicines called SGLT2 (sodium-glucose co-transporter 2) inhibitors) and metformin hydrochloride (which belongs to a class of medicines called biguanides). Jardiamet is an anti-diabetes medicine where two different ingredients work together to control blood sugar levels by increasing the amount of glucose expelled in urine, and lowering the amount of sugar made by your body.

Jardiamet is used to lower blood sugar levels in adults and children aged 10 years and older with type 2 diabetes mellitus. It 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 certain other anti-diabetic medicines such as:
 - sulfonylurea
 - pioglitazone
 - insulin
 - linagliptin.

If you have type 2 diabetes mellitus and cardiovascular disease, empagliflozin (one of the active ingredients in Jardiamet) can be used to reduce your risk of dying from your cardiovascular disease.

2. What should I know before I use Jardiamet?

Warnings

Do not use Jardiamet if you:

- are allergic to empagliflozin or metformin hydrochloride (the active ingredients in Jardiamet), or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine. Some of the symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.

- have any type of metabolic acidosis such as lactic acidosis, diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies build up in the blood - you may notice this as an unusual fruity odour on your breath, difficulty breathing, confusion and frequent urination)
- have had a diabetic pre-coma
- have problems with your kidneys
- have problems with your liver
- have a severe infection
- are dehydrated
- are treated for acute heart failure or have recently had a heart attack

- have severe problems with your circulation (such as shock)
- have severe breathing difficulties
- have blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate)
- have significant blood loss
- have gangrene
- have inflammation of the pancreas (pancreatitis), symptoms include severe upper stomach pain, often with nausea and vomiting
- drink excessive alcohol (all the time or "binge" drinking).

Talk to your doctor about when to stop taking Jardiamet and when to start taking it again if you:

- are going to have an X-ray where you will be injected with an iodinated contrast (dye)
- are planning to have surgery (including where the use of insulin is essential).

Discard any other medicines containing metformin or empagliflozin that your doctor might have prescribed to you in the past and that you may still have in your possession.

Jardiamet contains empagliflozin and metformin. If you have more than one metformin-containing medicine in your possession you may accidentally take too much (overdose). Accidentally taking too much metformin can cause a very serious side effect called lactic acidosis.

ACCIDENTAL METFORMIN OVERDOSING IS A SIGNIFICANT SAFETY RISK.

Ask your doctor or pharmacist if you are unsure if you have any other medicines containing metformin.

Metformin is sold under many different brand names in Australia. Your doctor or pharmacist will know which other medicines also contain metformin.

Tell your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have type 1 diabetes, a condition where your body does not produce insulin. Jardiamet should not be used to treat type 1 diabetes.
- are sick, have diarrhoea or fever, or if you are not able to eat or drink. These conditions can cause dehydration. Your doctor may ask you to stop taking Jardiamet until you recover to prevent loss of too much body fluid.
- have a serious infection of the kidney or the urinary tract with fever. Your doctor may ask you to stop taking Jardiamet until you have recovered.
- have heart problems, history of low blood pressure, or are 75 years of age or older. Increased passing of urine due to the medicine may affect fluid balance in your body and increase your risk of dehydration.
- are 85 years of age or older. You should not start taking Jardiamet 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 this medicine if you are pregnant or intending to become pregnant.

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

Do not breastfeed if you are taking this medicine.

Metformin, one of the active ingredients in Jardiamet passes into human breast milk and could affect your baby. It is not known whether the active ingredient, empagliflozin passes into human breast milk.

Children

Do not give this medicine to a child under the age of 10 years.

- Safety and effectiveness in children younger than 10 years has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Jardiamet.

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.

Discard any other medicines containing metformin or empagliflozin that your doctor might have prescribed to you in the past and that you may still have in your possession.

Jardiamet contains empagliflozin and metformin. If you have more than one metformin-containing medicine in your possession you may accidentally take too much (overdose).

Jardiamet may affect how well other medicines work and some medicines can affect how well Jardiamet works. These include:

- an antibiotic medicine used to treat certain infections such as tuberculosis (rifampicin)
- a medicine used to treat reflux and ulcers (cimetidine)
- medicines used to treat diseases that involve inflammation, like asthma and arthritis (corticosteroids)
- specific medicines for the treatment of high blood pressure (ACE inhibitors, angiotensin II receptor antagonists, calcium channel blockers, beta blockers)
- medicines used to prevent blood clots, such as warfarin
- medicines which increase urine production (diuretics)
- some medicines used to treat asthma (salbutamol or terbutaline)

- medicines used to relieve pain, swelling and other symptoms of inflammation (NSAIDs (non-steroidal anti-inflammatory drugs) such as aspirin, diclofenac, ibuprofen, meloxicam, naproxen or piroxicam, and selective COX II inhibitors such as celecoxib, parecoxib, etoricoxib)
- iodinated contrast agents (which you may receive while having an X-ray)
- alcohol-containing medicines
- a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits) (tetracosactrin)
- a medicine used to treat endometriosis (danazol)
- a medicine used to treat schizophrenia and other mental illnesses (chlorpromazine)
- a medicine used to treat and prevent mood disorders (lithium)
- medicines used in the treatment of HIV and chronic hepatitis C infections (dolutegravir, daclatasvir)
- medicines used in the treatment of certain cancers (crizotinib, olaparib, vandetanib)
- medicines used to control fits (seizures), chronic pain or glaucoma (topiramate, zonisamide, acetazolamide, dichlorphenamide).

These medicines may be affected by Jardiamet or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor, pharmacist or diabetes educator can tell you what to do if you are taking any of these medicines. They also have more information on medicines to be careful with or avoid while taking this medicine.

4. How do I use Jardiamet?

How to take it

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

- **Take Jardiamet exactly as your doctor or pharmacist has told you.**
- Your doctor will tell you how many Jardiamet tablets to take and how often you should take them.
- The usual dose is one Jardiamet tablet twice a day.

When to take Jardiamet

- **Swallow the tablets whole with a full glass of water during or after meals.** This will lessen the chance of a stomach upset.
- **Jardiamet should be used about 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.

If you forget to use Jardiamet

Jardiamet should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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 have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you use too much Jardiamet

If you think that you have used too much Jardiamet, 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 Jardiamet?

Things you should do

If you are about to be started on any new medicine, remind your doctor, dentist, and pharmacist that you are taking Jardiamet.

Talk to your doctor about when to stop taking Jardiamet and when to start taking it again if you are about to have surgery or an examination such as an X-ray or scan requiring an injection of iodinated contrast (dye).

If you are intending to become pregnant or are pregnant talk to your doctor about alternative medications to control your blood glucose level. It is important your blood glucose levels are as close to normal as possible at this time.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may want to perform blood tests to check your kidneys and vitamin B12 levels while you are taking Jardiamet.

Follow your doctor's and/or dietician's advice on diet, drinking alcohol and exercise. 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 doctor while taking Jardiamet.

Make sure you check your blood glucose 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.

Tell your doctor if you become ill or dehydrated, or experience stress, injury, fever, infection, or need surgery. Your blood glucose may become difficult to control at these times. You may also be at greater risk of developing a serious condition called lactic acidosis or diabetic ketoacidosis. During these times, your doctor may temporarily replace Jardiamet with insulin.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia (low blood sugar levels) and hyperglycaemia (high blood sugar levels) and know how to treat them.

Things you should not do

- **Do not stop using this medicine suddenly or lower the dosage without checking with your doctor.**
- **Do not take Jardiamet to treat any other complaints unless your doctor tells you to.**

- **Do not give your medicine to anyone else, even if they have the same condition as you.**

Hypoglycaemia

Jardiamet does not normally cause hypoglycaemia, although you may experience it if you take certain other medicines.

Signs of hypoglycaemia may include:

- weakness, trembling or shaking
- sweating
- light-headedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated quickly, these symptoms may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

At the first signs of hypoglycaemia, you need to raise your blood glucose quickly. You can do this by taking one of the following:

- 5-7 jelly beans
- 3 teaspoons of sugar or honey
- half a can of non-diet soft drink
- 2-3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

Also be careful when doing any of the following things, which may increase the risk of your blood glucose becoming too low:

- drinking alcohol
- not eating enough
- doing unexpected or vigorous exercise.

Hyperglycaemia

If you notice the return of any signs of hyperglycaemia, contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Jardiamet than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Driving or using machines

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

Jardiamet may cause dizziness in some people when taken with other anti-diabetic medicines, such as sulfonylurea or insulin, as your risk of getting low blood sugar is higher.

This may cause dizziness, light-headedness, tiredness, drowsiness in some people. Low blood glucose levels may also slow your reaction time and 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 glucose 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 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.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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.

Less serious side effects

Less serious side effects	What to do
Symptoms of a genital yeast infection <ul style="list-style-type: none">• genital burning, redness, pain and discharge Other less serious side effects	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
<ul style="list-style-type: none"> ● passing more urine than normal ● itching ● loss in appetite ● loss of taste ● thirst ● diarrhoea or stomach ache ● feeling sick (nausea), vomiting ● constipation. 	

Serious side effects

Serious side effects	What to do
<p data-bbox="199 1265 750 1377">Symptoms of low blood sugar (hypoglycaemia)</p> <ul style="list-style-type: none"> ● sweating ● weakness ● hunger ● dizziness ● trembling ● headache ● flushing or paleness ● numbness 	<p data-bbox="810 1265 1316 1489">Speak to your doctor as soon as possible if you have any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> ● a fast pounding heartbeat. <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 Jardiamet.</p> <p>Symptoms of a urinary tract infection</p> <ul style="list-style-type: none"> ● burning sensation when passing urine ● urine that appears cloudy ● pain in the pelvis or mid-back ● straining or pain when passing urine <p>Symptoms of dehydration</p> <ul style="list-style-type: none"> ● unusual thirst ● light-headedness, or dizziness upon standing 	

Serious side effects	What to do
<ul style="list-style-type: none"> • fainting or loss of consciousness 	

Very serious side effects

Very serious side effects	What to do
<p>Effects on Genital organs</p> <ul style="list-style-type: none"> • Swelling of the penis that makes it difficult to pull back the skin around the tip of the penis (uncircumcised men) <p>Symptoms of Fournier's gangrene</p> <ul style="list-style-type: none"> • pain, tenderness, itching, or swelling in the genital or back passage area • fever • generally feeling unwell <p>Symptoms of an allergic reaction:</p> <ul style="list-style-type: none"> • sudden onset of hives, itching or skin rash 	<p>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</p>

Very serious side effects	What to do
<ul style="list-style-type: none"> ● swelling of the face, lips or tongue which may lead to difficulty swallowing or breathing. <p>Symptoms of diabetic ketoacidosis:</p> <ul style="list-style-type: none"> ● 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. <p>In rare cases, empagliflozin, one of the active substances in Jardiamet can cause a serious side effect called diabetic ketoacidosis. The symptoms of diabetic ketoacidosis may continue</p>	

Very serious side effects	What to do
<p>in some patients after they stop taking Jardiamet.</p> <p>Symptoms of lactic acidosis</p> <ul style="list-style-type: none"> ● feeling cold (especially in your arms and legs) ● feeling very weak, tired ● feeling light-headed, dizzy ● severe nausea or vomiting ● feeling uncomfortable ● muscle pain ● drowsiness ● abdominal pain ● unexplained weight loss ● irregular heartbeat ● rapid or difficult breathing <p>In rare cases, metformin, one of the active substances in Jardiamet can cause a serious side effect called lactic acidosis.</p>	

Very serious side effects	What to do
This is a medical emergency that can cause death. It is caused by build-up of lactic acid in your blood.	

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. 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 Jardiamet contains

<p>Active ingredient (main ingredient)</p>	<ul style="list-style-type: none"> ● empagliflozin ● metformin hydrochloride
<p>Other ingredients (inactive ingredients)</p>	<ul style="list-style-type: none"> ● copovidone ● maize starch ● colloidal anhydrous silica ● magnesium stearate. ● hypromellose ● titanium dioxide ● macrogol 400 ● purified talc ● iron oxide yellow (5 mg/500 mg, 5 mg/850 mg, 5 mg/1000 mg tablets) ● iron oxide black (12.5 mg/500 mg, 12.5 mg/850 mg, 12.5 mg/1000 mg tablets) ● iron oxide red (12.5 mg/500 mg, 12.5 mg/850 mg, 12.5 mg/1000 mg tablets).
<p>Potential allergens</p>	<p>Not applicable</p>

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What Jardiamet looks like

Jardiamet 5 mg/500 mg tablets (AUST R 229815) are orange yellow, oval, biconvex film-coated tablets. One side is debossed with the Boehringer Ingelheim company symbol and "S5" the other side is debossed with "500".

Jardiamet 5 mg/850 mg tablets (AUST R 229816) are yellowish white, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and "S5", the other side is debossed with "850".*

Jardiamet 5 mg/1000 mg tablets (AUST R 229817) are brownish yellow, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and "S5", the other side is debossed with "1000".

Jardiamet 12.5 mg/500 mg tablets (AUST R 229818) are pale brownish purple, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and "S12", the other side is debossed with "500".

Jardiamet 12.5 mg/850 mg tablets (AUST R 229819) are pinkish white, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and "S12", the other side is debossed with "850".*

Jardiamet 12.5 mg/1000 mg tablets (AUST R 229820) are dark brownish purple, oval, biconvex film-coated tablets. One side is debossed with Boehringer Ingelheim company symbol and "S12", the other side is debossed with "1000".

Jardiamet is available in blister packs containing 14 (sample) and 60 tablets.

* Not distributed in Australia.

Who distributes Jardiamet

Jardiamet is supplied in Australia by:

Boehringer Ingelheim Pty Limited

ABN 52 000 452 308

Sydney NSW

www.boehringer-ingelheim.com.au

This leaflet was updated in April 2025.

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