

## 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.

### 1. Why am I using COZAAR?

COZAAR contains the active ingredient losartan potassium. COZAAR is used to lower high blood pressure, which doctors call hypertension. For more information, see Section [1. Why am I using COZAAR?](#) in the full CMI.

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

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

**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 COZAAR?](#) in the full CMI.

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

Some medicines may interfere with COZAAR 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 COZAAR?

- Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines.

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

### 5. What should I know while using COZAAR?

<b>Things you should do</b>	<ul style="list-style-type: none"> <li>Remind any doctor, dentist or pharmacist you visit that you are using COZAAR.</li> <li>Go to your doctor regularly for a check-up. Have your blood pressure checked when your doctor says, to make sure COZAAR is working.</li> <li>If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up</li> <li>Make sure you drink enough water during exercise and hot weather when you are taking COZAAR, especially if you sweat a lot.</li> <li>If you have excessive vomiting and/or diarrhoea while taking COZAAR, tell your doctor.</li> <li>If your doctor has prescribed potassium tablets for you, continue taking them.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>Do not give COZAAR to anyone else, even if they have the same condition as you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>COZAAR may cause dizziness or light-headedness in some people. Make sure you know how you react to COZAAR before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>If you drink alcohol, dizziness or light-headedness may be worse.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>Keep it in a cool dry place where the temperature stays below 30°C.</li> <li>Keep your tablets in the blister pack until it is time to take them.</li> </ul>

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

### 6. Are there any side effects?

Common side effects include dizziness, lightheadedness, tiredness or weakness, spinning sensation, generally feeling unwell, increased sensitivity of the skin to the sun and an inability to get or maintain an erection. Serious side effects include skin rash, shortness of breath, sore muscles not caused by exercise, bleeding or bruising more easily than normal or symptoms of an allergic reaction.

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.

## Consumer Medicine Information (CMI)

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

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

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

### 1. Why am I using COZAAR?

**COZAAR contains the active ingredient losartan potassium.** COZAAR belongs to a group of medicines, called angiotensin II receptor antagonists. It works to lower your blood pressure by relaxing your blood vessels. In addition, COZAAR slows the progression of kidney disease in people who have type 2 diabetes mellitus with protein in the urine.

COZAAR is not addictive.

**COZAAR is used to lower high blood pressure, which doctors call hypertension.**

**COZAAR is also used to slow the progression of kidney disease in people who have type 2 diabetes mellitus (also known as non-insulin dependent diabetes) with protein in their urine (which doctors call proteinuria).**

#### Hypertension:

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays high, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease or kidney failure. COZAAR helps to lower your blood pressure.

#### Type 2 Diabetes Mellitus:

Type 2 diabetes mellitus is a condition in which the body's cells do not respond to the effects of insulin or too little insulin is produced, resulting in an elevated blood (sugar) level, known as hyperglycaemia.

Insulin maintains the appropriate level of glucose in the blood by transporting it into the body's cells so that they can produce energy or store glucose until it's needed.

Hyperglycaemia can lead to serious problems with your heart, eyes, circulation or kidneys. When kidney damage occurs, its ability to filter blood is reduced, and proteins in the blood are lost in the urine. This may eventually lead to kidney failure. In people who have type 2 diabetes mellitus with protein in their urine, COZAAR helps to slow the worsening of kidney disease and reduce the need for dialysis or kidney transplantation.

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

#### Warnings

**Do not use COZAAR if:**

- you are pregnant or breast-feeding
- you are allergic to losartan potassium, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- the packaging is torn or shows signs of tampering.

**Check with your doctor if you:**

- have any other medical conditions especially kidney disease or liver problems, or have had these in the past.
- take any medicines for any other condition
- you are taking other medicines that may increase serum potassium (see Section [3. What if I am taking other medicines?](#)).
- you have recently had excessive vomiting or diarrhoea
- you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

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

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

**The use of COZAAR while you are pregnant or breast-feeding is not recommended.**

Your baby may absorb this medicine in the womb. COZAAR can cause harm or death to an unborn baby. Talk to your doctor about other ways to lower your blood pressure if

you plan to become pregnant. If you get pregnant while taking COZAAR tell your doctor right away. It is not known whether COZAAR passes into breast milk, therefore it is not recommended to be taken while you are breast-feeding.

### Use in children

Do not give COZAAR to a child. There is no experience with the use of COZAAR in children.

## 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.

**Some medicines may interfere with COZAAR and affect how it works.**

**Medicines that may increase the effect of COZAAR include:**

- other blood pressure medicines
- diuretic tablets, also called fluid or water tablets, including potassium-sparing diuretics
- indomethacin.

**Medicines that may reduce the effect of COZAAR include:**

- non-steroidal anti-inflammatory drugs (NSAIDs) or COX-2 inhibitors, medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- grapefruit juice (which should be avoided while taking COZAAR)

**Medicines that may increase serum potassium when taken with COZAAR include:**

- potassium tablets
- potassium-containing salt substitutes
- other medicines that may increase serum potassium (e.g., trimethoprim-containing products).

**Medicines that may be affected when taken with COZAAR include:**

- lithium (a medicine used to treat mood swings and some types of depressions)

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

## 4. How do I use COZAAR?

### How much to take

- Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines.
- For high blood pressure: For most patients, the usual starting dose is one 50 mg tablet taken once a day. Some patients may need a lower starting dose. The dose may need to be increased depending on your blood pressure. Most patients take between 25 to

100 mg each day, taken as a single dose or in divided doses.

- For type 2 diabetes mellitus with protein in the urine: The usual starting dose is one 50 mg tablet taken once a day. The dose may be increased to 100 mg once a day depending on your blood pressure.
- COZAAR helps control your high blood pressure, but does not cure it. Therefore COZAAR must be taken every day. Follow the instructions provided and use COZAAR until your doctor tells you to stop.

### When to take COZAAR

- It does not matter whether you take COZAAR before or after food.
- Take your COZAAR at about the same time each day. Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

### How to take COZAAR

- Swallow COZAAR with a glass of water.

### If you forget to take COZAAR

COZAAR 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 tablet(s) 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.**

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

### If you take too much COZAAR

If you take too many tablets, you will probably feel light-headed or dizzy.

If you think that you have taken too much COZAAR, 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 COZAAR?

### Things you should do

- Have your blood pressure checked when your doctor says, to make sure COZAAR is working.
- If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy while taking COZAAR, especially if you are also taking a diuretic (fluid tablet). This may become worse if you stand up quickly as your blood pressure may fall. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. This problem is not common. If it occurs and gets worse or continues, talk to your doctor.

- **If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking COZAAR.**

- **Make sure you drink enough water during exercise and hot weather when you are taking COZAAR, especially if you sweat a lot.**

If you do not drink enough water while taking COZAAR, you may faint or feel light-headed or sick. This is because your body doesn't have enough fluid and your blood pressure is low. If you continue to feel unwell, tell your doctor.

- **If you have excessive vomiting and/or diarrhoea while taking COZAAR, tell your doctor.**

This can also mean that you are losing too much water and your blood pressure may become too low.

- **If your doctor has prescribed potassium tablets for you, continue taking them.**

COZAAR contains a very small amount of potassium, but this does not replace any potassium tablets that you may be taking.

- **Go to your doctor regularly for a check-up.**

Your doctor may occasionally do a blood test to check your potassium level in the blood and to see how your kidneys are working.

#### **Call your doctor straight away if you:**

- become pregnant while taking COZAAR. Your doctor needs to know immediately so that COZAAR can be replaced by another medicine.

Remind any doctor, dentist or pharmacist you visit that you are using COZAAR.

#### **Things you should not do**

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

#### **Things that would be helpful for your blood pressure**

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Alcohol - your doctor may advise you to limit your alcohol intake.
- Diet - eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- Exercise - regular exercise helps to reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting

any exercise, ask your doctor about the best kind of programme for you.

- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.
- Smoking - your doctor may advise you to stop smoking or at least cut down.
- Weight - your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

#### **Driving or using machines**

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

As with many other medicines used to treat high blood pressure, COZAAR may cause dizziness or light-headedness in some people. Make sure you know how you react to COZAAR before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

#### **Drinking alcohol**

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

If you drink alcohol, dizziness or light-headedness may be worse.

#### **Looking after your medicine**

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

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 young 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.

## Less serious side effects

Less serious side effects	What to do
<b>Nervous system-related:</b> <ul style="list-style-type: none"><li>dizziness</li></ul> <b>Skin-related:</b> <ul style="list-style-type: none"><li>increased sensitivity of the skin to sun</li></ul> <b>Reproductive system or breast-related:</b> <ul style="list-style-type: none"><li>inability to get or maintain an erection</li></ul> <b>General conditions:</b> <ul style="list-style-type: none"><li>lightheadedness</li><li>tiredness or weakness</li><li>spinning sensation</li><li>generally feeling unwell</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>
<b>Respiratory-related:</b> <ul style="list-style-type: none"><li>cough</li></ul>	<b>Tell your doctor if you develop cough.</b>

## Serious side effects

Serious side effects	What to do
<b>Allergic reaction:</b> <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 pinkish, itchy swellings on the skin, also called hives or nettle rash</li><li>swelling in the intestine</li></ul>	<b>Stop taking COZAAR immediately, call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>
<b>Skin-related:</b> <ul style="list-style-type: none"><li>skin rash, itchiness (may be symptoms of an allergic reaction)</li></ul> <b>Muscle/skeleton-related:</b> <ul style="list-style-type: none"><li>aching muscles, not caused by exercise</li></ul> <b>Blood-related:</b> <ul style="list-style-type: none"><li>signs of anaemia, such as tiredness, being short of breath, and looking pale</li><li>bleeding or bruising more easily than normal</li></ul>	<b>Tell your doctor immediately if you notice any of these side effects. You may need medical attention.</b>  <b>These side effects are not common.</b>

**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.

## 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 COZAAR contains

<b>Active ingredient (main ingredient)</b>	losartan potassium 50 mg per tablet
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>microcrystalline cellulose</li><li>lactose monohydrate</li><li>pregelatinised maize starch</li><li>magnesium stearate</li><li>hypromellose</li><li>hypromellose</li><li>titanium dioxide</li><li>carnauba wax</li></ul>
<b>Potential allergens</b>	<ul style="list-style-type: none"><li>Lactose</li><li>COZAAR does not contain gluten, sucrose, tartrazine or any other azo dyes.</li></ul>

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

### What COZAAR looks like

COZAAR is a white, oval shaped tablet with "952" marked on one side and scored on the other side. (Aust R 54809).

A pack of COZAAR contains 30 tablets.

### Who distributes COZAAR

Organon Pharma Pty Limited  
Level 5, 66 King St  
Sydney NSW 2000  
Australia

This leaflet was prepared in March 2025.

S-WPPI-OG0954-T-102024

RCN 100004247-AU