Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking COZAVAN?

COZAVAN contains the active ingredient losartan. COZAVAN is used to lower high blood pressure, which doctors call hypertension. For more information, see Section 1. Why am I taking COZAVAN? in the full CMI.

2. What should I know before I take COZAVAN?

Do not use if you have ever had an allergic reaction to COZAVAN 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 take COZAVAN? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with COZAVAN 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 take COZAVAN?

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 take COZAVAN? in the full CMI.

5. What should I know while taking COZAVAN?

Things you should do	 Remind any doctor, dentist, or pharmacist you visit that you are taking COZAVAN. Go to your doctor regularly for a check-up. Have your blood pressure checked when your doctor says, to make sure COZAVAN is working. If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up. Make sure you drink enough water during exercise and hot weather when you are taking COZAAR, especially if you sweat a lot. If you have excessive vomiting and/or diarrhoea while taking COZAVAN, tell your doctor. If your doctor has prescribed potassium tablets for you, continue taking them.
Things you should not do	Do not give COZAVAN to anyone else, even if they have the same condition as you.
Driving or using machines	COZAVAN may cause dizziness or light-headedness in some people. Make sure you know how you react to COZAVAN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.
Drinking alcohol	If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	 Keep your tablets in a cool dry place where the temperature stays below 25°C. Keep your tablets in the original pack until it is time to take them.

For more information, see Section 5. What should I know while taking COZAVAN? in the full CMI.

6. Are there any side effects?

Common side effects include dizziness, light-headedness, 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 <u>6. Are there any side effects?</u> in the full CMI.

COZAVAN®

Active ingredient(s): losartan potassium

Consumer Information (CMI)

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

Where to find information in this leaflet:

- 1. Why am I taking COZAVAN?
- 2. What should I know before I take COZAVAN?
- 3. What if I am taking other medicines?
- 4. How do I take COZAVAN?
- 5. What should I know while taking COZAVAN?
- <u>6.</u> <u>Are there any side effects?</u>
- 7. Product details

1. Why am I taking COZAVAN?

COZAVAN contains the active ingredient losartan.

COZAVAN 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, COZAVAN slows the progression of kidney disease in people who have type 2 diabetes mellitus with protein in the urine.

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

COZAVAN 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. COZAVAN 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, COZAVAN helps to slow the worsening of kidney disease and reduce the need for dialysis or kidney transplantation.

COZAVAN is not addictive.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I take COZAVAN?

Warnings

Do not take COZAVAN if:

- you are pregnant or breastfeeding.
- you are allergic to losartan, or any of the ingredients listed at the end of this leaflet.
 Some of the symptoms of an allergic reaction may include:
 - o skin rash, itching or hives
 - o swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
 - o wheezing or shortness of breath.

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 expiry date printed on the pack has passed, or if the packaging is torn or show sign of tampering.
 Return it to your pharmacist for disposal.

Check with your doctor if you:

- have, or have had, any medical conditions, especially kidney disease or liver problems.
 - Your doctor may want to take special care if you have any of these conditions.
- take any medicines for any other condition.
- are taking other medicines that may increase serum potassium (see Section 3. What if I am taking other medicines?).
- have recently had excessive vomiting or diarrhoea.
- 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

Tell your doctor if you are pregnant or plan to become pregnant.

Tell to your doctor if you are breastfeeding or plan to breastfeed.

The use of COZAVAN while you are pregnant or breastfeeding is not recommended.

Your baby may absorb this medicine in the womb. COZAVAN 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 COZAVAN tell your doctor right away.

It is not known whether COZAVAN passes into breast milk, therefore it is not recommended to be taken while you are breastfeeding.

Use in children

Do not give COZAVAN to a child. There is no experience with the use of COZAVAN 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 COZAVAN and affect how it works.

Medicines that may <u>increase</u> the effect of COZAVAN include:

- other blood pressure medicines
- diuretic tablets, also called fluid or water tablets, including potassium-sparing diuretics
- medicines used to relieve pain, swelling, and other symptoms of inflammation, for example indomethacin.

Medicines that may <u>reduce</u> the effect of COZAVAN 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 COZAVAN).

Medicines that <u>may increase serum potassium when</u> <u>taken with</u> COZAVAN 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 COZAVAN 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 COZAVAN.

You may need to take different amounts of your medicine, or you may need to take different medicines.

4. How do I take COZAVAN?

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.

 COZAVAN helps control your high blood pressure but does not cure it. Therefore, COZAVAN must be taken every day. Follow the instructions provided and use COZAVAN until your doctor tells you to stop.

When to take COZAVAN

- It does not matter whether you take COZAVAN before or after food.
- Take your COZAVAN at about the same time each day.
 Taking your tablets 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 COZAVAN

• Swallow COZAVAN with a glass of water.

If you forget to take COZAVAN

COZAVAN should be taken 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 tablets 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 miss more than one dose, or are not sure what to do, check with your doctor or pharmacist.

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

If you take too much COZAVAN

If you take too many tablets, you will probably feel lightheaded or dizzy.

If you think that you or anyone else has taken too much COZAVAN, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking COZAVAN?

Things you should do

- Have your blood pressure checked when your doctor says, to make sure COZAVAN is working.
- Before starting any new medicine, tell your doctor or pharmacist that you are taking COZAVAN.
- 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 COZAVAN, 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.

- Tell all the doctors, dentists or pharmacists who are treating you that you are taking COZAVAN.
- If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking COZAVAN.
- Make sure you drink enough water during exercise and hot weather when you are taking COZAVAN, especially if you sweat a lot.

If you do not drink enough water while taking COZAVAN, 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 COZAVAN, 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.

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

- Visit your doctor regularly so they can check your progress.
 - Your doctor may occasionally ask you to do a blood test to check your potassium level in the blood and to see how your kidneys are working.
- Tell your doctor if, for any reason, you have not taken COZAVAN exactly as prescribed.

Otherwise your doctor may adjust your treatment unnecessarily.

Call your doctor straight away if you:

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

Things you should not do

- Do not give COZAVAN to anyone else, even if they have the same condition as you.
- Do not take COZAVAN for a longer time than your doctor has prescribed.
- Do not let yourself run out of COZAVAN over the weekend or on holidays.
- Do not use COZAVAN to treat any other conditions unless your doctor tells you to.

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. Reducing your saturated fat intake (eat less fatty meats, full fat dairy products, butter, coconut and palm oils, most take-away foods, commercially-baked products).
- Exercise be active, regular exercise helps to reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Progress over time, to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Can be accumulated in shorter bouts of 10 minutes duration. If you have been prescribed anti-angina medicine, carry it with you when being physically active. 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 program 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 and avoid second-hand smoke.
- Weight maintain a healthy 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.

- Discuss your lifestyle and lifestyle plans with your doctor.
- For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Driving or using machines

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

As with many other medicines used to treat high blood pressure, COZAVAN may cause dizziness, drowsiness, lightheadedness or affect alertness in some people. This effect may continue the following day. Make sure you know how you react to COZAVAN before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed.

Particular care is recommended when you are first taking COZAVAN or if the amount of COZAVAN or any other medicine you are taking is increased or decreased.

Drinking alcohol

Tell your doctor if you drink alcohol.

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

Use in elderly

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing or have a cold sweat or feel dizzy or light-headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Looking after your medicine

- Store below 25°C.
- Keep your tablets in the original pack until it is time to take them. If you take the tablets out the original pack, they may not keep well.

Follow the instructions on 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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Nervous system-related:	Speak to your
• dizziness	doctor if you have any of
Skin-related:	these less serious side effects and they worry you.
increased sensitivity of the skin to sun	
Reproductive system or breast- related:	
inability to get or maintain an erection.	
General conditions:	
 lightheadedness tiredness or weakness spinning sensation generally feeling unwell 	
Respiratory-related:	Tell your doctor
• cough	if you develop cough.

Serious side effects

Serious side effects	What to do
swelling of the face, lips, mouth, tongue, or throat which may cause difficulty in swallowing or breathing. severe and sudden onset of pinkish, itchy swellings on the skin, also called hives or nettlerash swelling in the intestine	Stop taking COZAVAN 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.

Serious side effects	What to do
Skin-related:	Tell your doctor
 skin rash, itchiness (may be symptoms of an allergic reaction) 	immediately if you notice any of these side effects. You
Muscle/skeleton-related:	may need
aching muscles, not caused by exercise	medical attention.
Blood-related:	
 signs of anaemia, such as tiredness, being short of breath, and looking pale bleeding or bruising more easily than normal 	These side effects are not common.

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 By reporting side effects, you can help provide more information on the safety of this medicines.

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 COZAVAN contains

Active ingredient (main ingredient)	losartan potassium 25 mg and 50 mg	
Other ingredients (inactive ingredients)	 microcrystalline cellulose lactose monohydrate pregelatinised maize starch magnesium stearate Opadry complete film coating system 20A58900 White (ID 13043) 	
Potential allergens	Lactose	

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

What COZAVAN looks like

COZAVAN 25 mg: white to off white, oval shaped biconvex film-coated tablet with "A" engraved on one side and "25" on the other side. (AUST R 156235).

COZAVAN 50 mg: white to off white, oval shaped biconvex film-coated tablet with "A50" engraved on one side and

has a central break line on the other side. (AUST R 156234).

A blister pack of COZAVAN contains 10 (as starter pack) or 30 tablets.

Who distributes COZAVAN

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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