

COZAAR[®]

losartan potassium

12.5 mg, 25 mg, 50 mg and 100 mg tablets

What is in this leaflet

This leaflet answers some common questions about COZAAR. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking COZAAR against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What COZAAR is used for

COZAAR lowers high blood pressure, which doctors call hypertension. If you have high blood pressure and a thickening of the left ventricle, the heart's main pumping chamber, your doctor has prescribed COZAAR to help lower the risk of cardiovascular events, such as stroke. It is also used to treat heart failure.

COZAAR also provides kidney protection by delaying the worsening of kidney disease in type 2 diabetic patients with protein in their urine (proteinuria). Kidney disease can be measured by testing the urine for protein.

High blood pressure

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.

Thickening of the Left Chamber of the Heart

High blood pressure causes the heart to work harder. Over time, this may cause the heart to thicken.

A thickening of the left ventricle of the heart is associated with an increased chance of experiencing a stroke. In patients with high blood pressure and a thickening of the left chamber of the heart, COZAAR has been shown to reduce the risk of cardiovascular events, such as stroke.

In patients with high blood pressure and the thickening of the left ventricle, COZAAR has been shown to decrease the risk of stroke and heart attack and to help patients live longer (see Use in Black Patients With High Blood Pressure and a Thickening of the Left Ventricle).

Heart Failure

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is **not** the same as heart attack and does **not** mean that the heart stops working. Some people develop heart failure after having had a heart attack. However, there are also other causes of heart failure.

Heart failure may start off with no symptoms, but as the condition progresses, you may feel short of breath or may get tired easily after light physical activity such as walking. You may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet. In severe heart failure, symptoms may occur even at rest.

COZAAR helps to treat heart failure. If you follow your doctor's advice, your ability to perform daily activities may improve. You may breathe more easily, feel less tired and have less swelling.

When used to treat heart failure, COZAAR is usually taken with other medicines, such as fluid tablets or digoxin. The fluid tablets help the kidney get rid of excess fluid from the body.

Type 2 Diabetes With Protein In The Urine

Type 2 diabetes is a disorder of your body's ability to convert food into energy. In people with type 2 diabetes, the body's cells do not respond to the effects of insulin or too little insulin is produced. In either case, glucose (sugar) cannot enter the body's cells. This causes a build up of sugar in the blood, which is known as hyperglycaemia or high blood sugar.

The deterioration that characterises kidney disease related to diabetes takes place in and around the blood-filtering units of the kidney. The kidney's ability to filter blood is reduced, and proteins in the blood are lost in the urine. Kidney disease can be measured by testing the urine for protein. Later in the disease, the kidneys lose their ability to remove waste products, such as creatinine and urea, from the blood. The progression of kidney disease is measured by testing the blood for these waste products. In type 2 diabetic patients with protein in the urine, COZAAR has been shown to slow the worsening of kidney disease and to reduce the need for dialysis or kidney transplantation.

How COZAAR works

COZAAR works by widening your blood vessels to make it easier for your heart to pump blood to all parts of your body. This helps to lower high blood pressure. COZAAR also helps to lower the risk of cardiovascular events, such as stroke, in patients with high blood pressure and a thickening of the left ventricle of the heart. In heart failure, this helps the heart to function better. In addition to these blood pressure effects, COZAAR also helps protect your kidneys if you have type 2 diabetes with protein in the urine.

COZAAR belongs to a new group of medicines, called angiotensin II receptor antagonists.

COZAAR is not addictive.

Before you take COZAAR

When you must not take it

Do not take COZAAR if:

- you are pregnant or breast-feeding.
Your baby may absorb this medicine in the womb and therefore there is a possibility of harm to the baby. It is not known whether COZAAR passes into breast milk, therefore it is not recommended to be taken while you are breast-feeding.
- you have an allergy to COZAAR or any of the ingredients listed at the end of this leaflet
- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.
if you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking COZAAR, talk to your doctor.

Use in Children

COZAAR has been studied in children. For more information, talk to your doctor.

Use in Black Patients With High Blood Pressure and a Thickening of the Left Ventricle

In a study in patients with high blood pressure and a thickening of the left chamber of the heart, COZAAR was shown to decrease the risk of stroke and heart attack, and help patients live longer. However, in this study, these benefits, when compared to another antihypertensive medicine called atenolol, did not apply to Black patients.

Before you start to take it

Tell your doctor if:

- you intend to become pregnant or plan to breast-feed.
COZAAR should not be used during pregnancy or while breast-feeding.
- you have any medical conditions, especially the following:
 - kidney disease
 - liver problems or have had these in the past
 - 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.

If you have not told your doctor about any of the above, tell them before you take any COZAAR.

Taking other medicines

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

Some medicines may affect the way others work. Also, some other medicines used to treat high blood pressure may have an additive effect with COZAAR in lowering your blood pressure. Examples include diuretics or fluid tablets. As a result you may need different amounts of your medicines.

In general, COZAAR has not been shown to interfere with other medicines. However, it is still important to tell your doctor and pharmacist if you are taking potassium supplements, potassium-sparing agents or salt substitutes containing potassium or any other medicines you are taking or plan to take. Also tell your doctor if you are taking certain pain and arthritis medicines or lithium (a medicine used to treat a certain kind of depression).

How to take 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. Take COZAAR only when prescribed by your doctor.

For high blood pressure

For most patients with high blood pressure, the usual starting dose is one 50 mg tablet taken once a day. Some people may need a lower starting dose. The dose may need to be increased depending on your blood pressure.

The usual dose of COZAAR for patients with high blood pressure with a thickening of the left ventricle of the heart is 50 mg taken once a day. The dose may be increased to 100 mg taken once daily.

For heart failure

The usual starting dose is 12.5 mg taken once a day. Your doctor will increase this dose step by step until the amount that is right for you has been achieved. The usual long term dose is 50 mg taken once a day.

Type 2 Diabetes with Protein in the Urine

The usual dose of COZAAR for most patients is 50 mg taken once a day. The dose may be increased to 100 mg taken once daily.

Follow all directions given to you by your doctor 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.

When to take it

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.

Swallow COZAAR with a glass of water or other liquid.

It does not matter whether you take COZAAR before or after food.

How long to take it

COZAAR helps control your high blood pressure, but does not cure it. Therefore COZAAR must be taken every day. Continue taking COZAAR for as long as your doctor prescribes.

If you forget to take it

If it is almost time for your next dose, 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 tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

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

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much COZAAR. Do this even if there are no signs of discomfort or poisoning.

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

While you are using COZAAR

Things you must do

If you become pregnant while taking COZAAR tell your doctor immediately.

Have your blood pressure checked when your doctor says, to make sure COZAAR is working.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking COZAAR.

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.

Continue taking potassium tablets if your doctor has prescribed these for you. COZAAR contains a very small amount of potassium, but this does not replace any potassium tablets that you may be taking.

Things you must not do

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

Things to be careful of

Be careful driving or operating machinery 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. If you drink alcohol, dizziness or light-headedness may be worse.

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.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking COZAAR.

COZAAR helps most people with high blood pressure, but it may have unwanted adverse effects in a few people. All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- dizziness
- light-headedness
- fatigue
- vertigo
- aching muscles, muscle tenderness or weakness, not caused by exercise
- joint pain
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- abnormal sense of taste
- vomiting
- increased sensitivity of the skin to sun

These are the common adverse effects of COZAAR. For the most part these have been mild.

Tell your doctor immediately if you notice any of the following:

- skin rash, itchiness

These may be serious adverse effects. Skin rash and itchiness may be symptoms of an allergic reaction. You may need medical attention. These adverse effects are not common.

If any of the following happen, stop taking COZAAR and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- 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

These are serious adverse effects. If you have them, you may have had a serious allergic reaction to COZAAR. You may need urgent medical attention or hospitalisation. These adverse effects are rare.

Some patients, especially those with type 2 diabetes with protein in the urine, may also develop increased levels of potassium in their blood. If you have kidney disease and type 2 diabetes with protein in the urine, and/or are taking potassium supplements, potassium-sparing agents or salt substitutes containing potassium, talk to your doctor.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using COZAAR

Storage

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

Keep it in a cool dry place where the temperature stays below 30°C and protect from light. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

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

Disposal

If your doctor tells you to stop taking COZAAR or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

COZAAR comes in four strengths of tablets:

- COZAAR 12.5 mg - a blue, oval-shaped tablet with "11" marked on one side and plain on the other.
- COZAAR 25 mg – a white, oval shaped tablet with "951" marked on one side and plain on the other. (Currently not available in New Zealand).
- COZAAR 50 mg - a white, oval-shaped scored tablet with "952" marked on one side and plain on the other.
- COZAAR 100 mg - a white, teardrop shaped tablet with "960" marked on one side and plain on the other.

A pack contains 30 tablets.

Ingredients

Active ingredient:

COZAAR 12.5 mg - 12.5 mg losartan potassium per tablet

COZAAR 25 mg – 25 mg losartan potassium per tablet

COZAAR 50 mg - 50 mg losartan potassium per tablet

COZAAR 100 mg – 100 mg losartan potassium per tablet

Inactive ingredients:

- microcrystalline cellulose
- lactose
- pregelatinised starch
- magnesium stearate
- hydroxypropylcellulose
- hypromellose
- titanium dioxide
- carnauba wax

The 12.5 mg tablet also contains indigo carmine aluminium lake (FD&C blue No. 2).

Supplier

COZAAR is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited

P O Box 99 851

Newmarket

Auckland

NEW ZEALAND

Tel: 0800 500 673

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