

Consumer Medicine Information

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.

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.

How it works

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.

Before you take COZAAR

When you must not take it

Do not take COZAAR if:

- **you are pregnant or breast-feeding**
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.
- **you have an allergy to COZAAR or any of the ingredients listed at the end of this leaflet**
- **you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.**
- **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.

Do not give COZAAR to a child.

There is no experience with the use of COZAAR in children.

Before you start to take it

Tell your doctor if:

1. **you intend to become pregnant or plan to breast-feed**
COZAAR should not be used during pregnancy or while breast-feeding.
2. **you are taking other medicines that may increase serum potassium (see Taking other medicines).**
3. **you have any medical conditions, especially the following:**
 - kidney disease
 - liver problems or have had these in the past.
4. **you have recently had excessive vomiting or diarrhoea**
5. **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 or substances and COZAAR may interfere with each other. These include:

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

- potassium tablets
- potassium-containing salt substitutes
- other medicines that may increase serum potassium (e.g., trimethoprim-containing products).
- medicines used to relieve pain, swelling, and other symptoms of inflammation, for example, indomethacin.
- lithium (a medicine used to treat mood swings and some types of depressions)
- grapefruit juice (which should be avoided while taking COZAAR)

These medicines may have an additive effect with COZAAR in lowering your blood pressure, or may affect how well it works, or may lead to increases in potassium in your blood. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking COZAAR.

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, 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.

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.

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 Poisons Information Centre (telephone 13 11 26), 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. Your doctor needs to know immediately so that COZAAR can be replaced by another medicine.

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.

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.

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.

Side 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 side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side 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
- lightheadedness
- tiredness or weakness

- spinning sensation
- generally feeling unwell
- increased sensitivity of the skin to sun
- inability to get or maintain an erection

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

Also, tell your doctor if you develop cough.

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

- skin rash, itchiness
- aching muscles, not caused by exercise
- signs of anaemia, such as tiredness, being short of breath, and looking pale
- bleeding or bruising more easily than normal

These may be serious side effects. Skin rash and itchiness may be symptoms of an allergic reaction. You may need medical attention. These side 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 nettle rash

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

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

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

After using COZAAR

Storage

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.

Keep it in a cool dry place where the temperature stays below 30°C. 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 one type of tablet:

- COZAAR 50 mg - white, oval shaped tablet with "952" marked on one side and scored on the other side.

A pack of COZAAR contains 30 tablets.

Ingredients

Active ingredient:

- COZAAR 50 mg - losartan potassium 50 mg per tablet

Inactive ingredients:

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

COZAAR does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

COZAAR is supplied in Australia by:

Organon Pharma Pty Limited
Building A, 26 Talavera Road,
Macquarie Park, NSW 2113 Australia

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