

COZAAR[®] TABLET

Losartan potassium (50 mg, 100 mg)

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What COZAAR is used for

COZAAR is an angiotensin II receptor antagonist which lowers blood pressure. 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.

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.

Why has my doctor prescribed COZAAR?

Your doctor has prescribed COZAAR because you have a condition known as hypertension (high blood pressure). In patients with high blood pressure and a 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 **“While you are using it”- Use in Black patients with high blood pressure and a thickening of the left ventricle**). Your doctor may also have prescribed COZAAR

because you have type 2 diabetes with protein in the urine. In type 2 diabetic patients with protein in the urine, COZAAR has been shown to slow the worsening of kidney disease.

How COZAAR works

COZAAR works by widening your blood vessels to make it easier for the heart to pump blood to all parts of your body. This helps to reduce 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 addition to these blood pressure effects, COZAAR also helps protect your kidneys if you have type 2 diabetes with protein in the urine.

Information for Patients with High Blood Pressure

What is blood pressure?

The pressure caused by your heart pumping blood to all parts of your body is called blood pressure. Without blood pressure there would be no circulation of blood in your body. Normal blood pressure is part of good health. Your blood pressure changes during the day depending on activity, stress and excitement.

Your blood pressure is made up of two numbers, for instance 120/80. The top number measures the force while your heart pumps. The bottom number measures the force at rest, between heartbeats.

What is high blood pressure (or hypertension)?

You have high blood pressure or hypertension if your blood pressure stays high even when you are calm and relaxed. High blood pressure

develops when blood vessels tighten, making it harder for blood to pass.

How do I know if I have high blood pressure?

There are usually no symptoms of high blood pressure. The only way of knowing that you have hypertension is to know your blood pressure. For that reason, you should have your blood pressure checked on a regular basis.

Why should high blood pressure be treated?

High blood pressure if left untreated can damage vital organs like the heart and the kidneys. You may feel fine and have no symptoms, but eventually hypertension can cause strokes, heart attacks, heart failure, kidney failure or blindness.

How should high blood pressure be treated?

Once high blood pressure is diagnosed, some treatments other than drugs may be recommended. Your doctor may recommend some changes in life-style. Your doctor may decide that you also need medicine to control your blood pressure. High blood pressure can be treated and controlled by taking medicines such as COZAAR.

Your doctor can tell you what your individual blood pressure target should be. Keep this number in mind and follow your doctor's advice on how to reach this target.

How does COZAAR treat high blood pressure?

COZAAR lowers blood pressure by specifically blocking a substance called angiotensin II. Angiotensin II normally tightens your blood vessels. Treatment with COZAAR allows them to relax. Although your

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doctor will be able to tell you that the medicine is working by measuring your blood pressure, you probably will feel no different while you are taking COZAAR.

What causes a 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.

Why should patients with a thickening of the left ventricle of the heart be treated?

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.

Information for Patients with Type 2 Diabetes and Protein in the Urine

What is Type 2 Diabetes?

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 buildup of sugar in the blood, which is known as hyperglycemia or high blood sugar.

Why should patients with Type 2 Diabetes with Protein in the Urine be treated?

The deterioration that characterizes 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.

Before you take COZAAR

When you must not use it

Do not take COZAAR if you are allergic to any of its ingredients.

Do not take COZAAR if you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

Before you start to use it

Tell your doctor or pharmacist about any medical problems you have or have had, and about any allergies. Tell your doctor if you have recently suffered from excessive vomiting or diarrhea. It is particularly important to tell your doctor if you have liver or kidney disease.

Taking other medicines

In general, COZAAR does not interact with food or other medicines you may be taking. You should, however, tell your doctor about all drugs that you are taking or plan to take, including those obtained without a prescription. It is important to tell your doctor if you are taking potassium supplements,

potassium-sparing agents or salt substitutes containing potassium. Also tell your doctor if you are taking certain pain and arthritis medicines, other blood pressure medicines, or lithium (a drug used to treat a certain kind of depression).

How to take COZAAR

How much to take

Your doctor will decide on the appropriate dose of COZAAR, depending on your condition and whether you are taking other medicines.

High Blood Pressure

The usual dose of COZAAR for most patients with high blood pressure is 50 mg taken once a day to control blood pressure over the 24-hour period.

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.

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.

When to take it

Take COZAAR every day, exactly as your doctor has instructed.

COZAAR can be taken with or without food. For convenience and to help you remember, try to take COZAAR at the same time each day.

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How long to take it

It is important to continue taking COZAAR for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

If you forget to take it

Try to take COZAAR daily as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

If you take too much (overdose)

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly.

While you are taking COZAAR

Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking COZAAR.
- Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give COZAAR to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Although COZAAR contains a very small amount of potassium, it cannot replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow his advice.

Use in pregnancy and breast-feeding

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

Use in children

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

Use in the elderly

COZAAR works equally well in and is equally well tolerated by most older and younger adult patients. Most older patients require the same dose as younger patients.

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.

Can I drive or operate machinery while using COZAAR?

Almost all patients can, but you should not perform tasks which may require special attention (for example, driving an automobile or operating dangerous machinery) until you know how you tolerate your medicine.

Side effects

Any medicine may have unintended or undesirable effects, so-called side effects. Some patients may experience dizziness, fatigue, lightheadedness, rash, hives, taste alteration, vomiting or increased sensitivity of the skin to sun. Your doctor or pharmacist has a more complete list. Tell your doctor or pharmacist promptly about these or any other unusual symptom.

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.

If you develop an allergic reaction involving swelling of the face, lips, throat and/or tongue which may cause difficulty in breathing or swallowing, stop taking COZAAR and contact your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting)

How can I learn more about COZAAR and my condition?

You may obtain further information from your physician or pharmacist, who has more detailed information about your condition and COZAAR.

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Storage and Disposal of COZAAR

Storage

- Store COZAAR at room temperature and protect from light. If the temperature rises above 30°C (86°F) for an extended period of time, you may store COZAAR in the refrigerator.
- Keep the container tightly closed. Do not open the blister pack until you are ready to take the medicine.
- Keep all medicines safely away from children.

Disposal

- Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year.
- You may obtain further information from your doctor or pharmacist, who has more detailed information.

Product description

What it looks like

COZAAR is available as 50 mg or 100 mg tablets.

COZAAR 50 mg: White oval, film-coated tablets with “952” debossed on one side and score-line on the other side.

COZAAR 100 mg: White, teardrop-shaped, film-coated tablet with “960” debossed on one side and plain on the other.

Ingredients

Active ingredient:

- COZAAR 50 mg contains 50 mg of losartan potassium as the active ingredient.

- COZAAR 100 mg contains 100 mg of losartan potassium as the active ingredient.

Inactive ingredients:

In addition, COZAAR contains the following inactive ingredients: microcrystalline cellulose, lactose hydrous, pregelatinized starch, magnesium stearate, hydroxypropyl cellulose, hydroxypropyl methylcellulose. COZAAR 50 mg and 100 mg tablets also contain carnauba wax and titanium dioxide

MAL number

COZAAR 50 MG TABLET:
MAL19963142AR

COZAAR 100 MG TABLET:
MAL20021160AR

Product Manufacturer

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Product Registration Holder

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