

PATIENT INFORMATION LEAFLET
INFORMATION FOR THE PATIENT ABOUT COZAAR®

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

COZAAR® Tablet

COZAAR® 100 Tablet

WHAT COZAAR CONTAINS

COZAAR (losartan potassium) is an oval white film-coated tablet which contains 50 mg of losartan potassium as the active ingredient.

COZAAR 100 (losartan potassium) is a white film-coated, teardrop-shaped tablet which contains 100 mg of losartan potassium as the active ingredient.

In addition, COZAAR and COZAAR 100 contain the following inactive ingredients: Microcrystalline cellulose, Lactose hydrous, Pregelatinised starch, Magnesium stearate, Hydroxypropyl cellulose, Hydroxypropyl methyl cellulose, Titanium dioxide and Carnauba wax.

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.

COZAAR is available as 50 mg and 100 mg tablets.

WHAT COZAAR IS USED FOR

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

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.

Your doctor has prescribed COZAAR because you have a condition known as hypertension or high blood pressure. 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.

BEFORE TAKING COZAAR

Do not take COZAAR:

- if you are allergic to any of its ingredients
- if you have had angio-oedema (swelling of the face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking an ACE inhibitor or an angiotensin receptor blocker such as COZAAR
- if you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart)
- if you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart
- if you have narrowing of the blood vessels to both kidneys or to a single kidney
- if you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride
- if you have severe kidney disease
- if you have liver disease
- if you are pregnant and breastfeeding (see **Pregnancy and Breastfeeding**)

Pregnancy and breast feeding

The use of COZAAR while you are pregnant or breast feeding is contra-indicated. If you are pregnant or become pregnant while taking COZAAR, stop taking COZAAR and talk to your doctor as soon as possible.

You should not take COZAAR if you are pregnant or breastfeeding or planning to become pregnant.

Take special care with COZAAR:

- if you have or have had any medical problems, and any allergies
- if you have recently suffered from excessive vomiting or diarrhoea
- if you have liver or kidney disease
- if you have porphyria

Taking COZAAR with food and drink:

COZAAR can be taken with or without food.

Use in children

There is no experience with the use of COZAAR in children. Therefore, COZAAR should not be given to children.

Use in 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.

Taking other medicines with COZAAR

In general, COZAAR does not interact with food or other medicines you may be taking. You should, however, tell your doctor about all medicines 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 or lithium (a drug used to treat a certain kind of depression).

If you are taking medicines on a regular basis, using the medicine at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery

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

HOW TO TAKE COZAAR

Take COZAAR every day, exactly as your doctor has instructed. Your doctor will decide on the appropriate dose of COZAAR, depending on your condition and whether you are taking other medicines. 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.

High blood pressure

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

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.

For convenience and to help you remember, try to take COZAAR at the same time each day.

Do not share medicines prescribed for you with any other person.

If you take more COZAAR than you should:

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

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take COZAAR:

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

SIDE EFFECTS

What undesirable effects may COZAAR have?

Any medicine may have unintended or undesirable effects, so-called side-effects. Some patients may experience dizziness, fatigue, light-headedness, rash or 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 symptoms.

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 and/or tongue which may cause difficulty in breathing or swallowing, stop taking COZAAR and contact your doctor immediately.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION

Store COZAAR in a dry place below 30 °C and protect from light. If the temperature rises above 30 °C 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 OUT OF REACH AND SIGHT OF CHILDREN.

Do not use this medicine after the month and year following EXPIRES/VERVAL on the carton.

PRESENTATION

COZAAR tablets are available in blister packs of 30.

COZAAR 100 tablets are available in opaque white blister packs of 30.

IDENTIFICATION OF COZAAR

COZAAR is a white, oval shaped film-coated tablet, scored one side, engraved '952' on the other side.

COZAAR 100 is a white, teardrop-shaped, film-coated tablet with "960" debossed on one side and plain on the other.

REGISTRATION NUMBERS

COZAAR: 29/7.1.3/0268

COZAAR 100: 36/7.1.3/0490

THE NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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