

COZAAR[®] COMP 100 / 25

Film-Coated Tablets

(Losartan potassium and hydrochlorothiazide)

PLEASE READ ALL OF THIS LEAFLET CAREFULLY BEFORE YOU START TO TAKE YOUR TABLETS, EVEN IF YOU HAVE JUST HAD A REPEAT PRESCRIPTION. SOME OF THE INFORMATION IN YOUR PREVIOUS LEAFLET MAY HAVE CHANGED.

Keep this leaflet. You may want to read it again.

WHAT IS IN YOUR TABLETS?

Active ingredients: There are two active ingredients in 'Cozaar'-Comp. These are losartan potassium and hydrochlorothiazide. 'Cozaar'-Comp 100/25 is available as yellow, oval, film-coated tablets marked '747' on one side, containing 91.6 mg of losartan, present as 100 mg of losartan potassium and 25 mg of hydrochlorothiazide.

Other ingredients: Hydroxypropylcellulose E463; hypromellose E464; lactose monohydrate; magnesium stearate E572; microcrystalline cellulose E460; pregelatinised maize starch; titanium dioxide E171; quinoline yellow aluminum lake E104; carnauba wax.

Although 'Cozaar'-Comp contains a very small amount of potassium, it cannot replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow the advice given.

'Cozaar'-Comp 100/25 Tablets are supplied in packs of 28 tablets.

HOW DO YOUR TABLETS WORK?

'Cozaar'-Comp contains two active ingredients. These are losartan potassium and hydrochlorothiazide. Losartan belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin II is a chemical occurring in the body, which tightens your blood vessels making it harder for the blood to pass through them and causing your blood pressure to increase. 'Cozaar'-Comp blocks this effect of angiotensin II, causing the blood vessels to relax. Hydrochlorothiazide works by making your kidneys pass more water and salt. Together, losartan and hydrochlorothiazide lower high blood pressure. Although your 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'-Comp.

MARKETING AUTHORISATION HOLDER AND MANUFACTURER

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The Marketing Authorisation Holder is Merck Sharp & Dohme Limited, Hertford Road, Hoddesdon, Hertfordshire EN11 9BU, UK.

WHY DO YOU NEED TO TAKE THESE TABLETS?

Your doctor has prescribed 'Cozaar'-Comp because you have a condition known as hypertension, or high blood pressure.

Blood pressure is the term given to the pressure produced by your heart pumping blood to all parts of your body. Your blood pressure is measured by two numbers, e.g. 120/80 mm Hg.

The top number measures the pressure while your heart beats and the bottom number measures the pressure in between heartbeats.

Normal blood pressure is part of good health. High blood pressure is caused when the blood vessels tighten and the measurement goes above the normal range for your age. There are usually no symptoms of high blood pressure and you will only know you have it if you have had your blood pressure measured.

Although you might feel quite well, if your high blood pressure is not treated, it can damage your heart and kidneys, and in some cases lead to stroke, heart attack, heart and/or kidney failure, or blindness.

High blood pressure can be treated and controlled with medicines such as 'Cozaar'-Comp. Your doctor may also recommend that you make some changes to your lifestyle to help your high blood pressure, such as losing weight, keeping alcohol intake moderate or avoiding it altogether, stopping smoking, and reducing the amount of salt in your diet. Your doctor may also encourage you to take more mild exercise.

ARE THERE PATIENTS WHO SHOULD NOT TAKE THESE TABLETS?

Yes, do not take the tablets if:

- (1) you are or think you may be pregnant
- (2) you are planning to become pregnant
- (3) you are breast-feeding
- (4) you are allergic to any of the ingredients
- (5) you are allergic to any sulphonamide-derived medicines (ask your doctor if you are not sure what sulphonamide-derived drugs are)
- (6) you are not passing urine
- (7) you have liver problems
- (8) you have kidney problems or are on dialysis.

'Cozaar'-Comp should not be given to children.

If you think any of these apply to you, do not take the tablets. Talk to your doctor first and follow the advice given.

WHAT ELSE SHOULD YOU KNOW BEFORE TAKING 'COZAAR'-COMP?

It is important to tell your doctor before taking 'Cozaar'-Comp if you suffer from gout, diabetes, lupus erythematosus, or if you are being treated with other diuretics (water tablets). In these cases, your doctor may need to adjust the dose of your medications.

Tell your doctor if you have recently suffered from excessive vomiting and/or diarrhoea or if you have parathyroid problems.

Tell your doctor if you have a condition called 'aortic stenosis' or 'outflow obstruction'.

If you have received a kidney transplant you should inform your doctor.

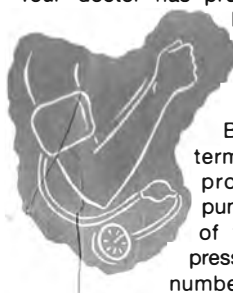
You should also tell your doctor if you have high levels of potassium in your blood (hyperkalaemia) or you are on a low potassium diet.

Before surgery and anaesthesia (even at the dentist), tell the doctor or dentist that you are taking 'Cozaar'-Comp, as there may be a sudden fall in blood pressure associated with the anaesthesia. In addition, if you are going to have a blood test, you should let your doctor know that you are taking 'Cozaar'-Comp. 'Cozaar'-Comp can affect the results of some diagnostic tests.

CAN YOU TAKE 'COZAAR'-COMP WITH OTHER MEDICINES?

In general, 'Cozaar'-Comp can be taken with other drugs. You should tell your doctor about all drugs that you are taking or plan to take, including those obtained without a prescription. You should also tell your doctor if you are taking any of the following:

- potassium supplements, potassium sparing agents, or potassium-containing salt substitutes
- rifampicin, a drug used in the treatment of tuberculosis (TB)
- fluconazole, a drug used for treating fungal infections such as thrush
- NSAIDs (non-steroidal anti-inflammatory drugs) such as indomethacin, used to treat patients with arthritis and for treating certain types of pain
- barbiturates, sedative drugs which may be used in the treatment of sleeplessness or epilepsy
- narcotics, morphine like drugs used for severe pain
- anti-diabetic drugs (medicines for the treatment of diabetes), including oral agents to lower blood sugar and insulin
- other drugs used to reduce blood pressure
- other diuretics (water tablets)
- resins which are used to reduce high cholesterol levels
- ACTH, used to test whether your adrenal glands are working properly
- corticosteroids, used to treat various conditions including rheumatism, arthritis, allergic conditions, certain skin diseases, asthma or certain blood disorders
- pressor amines, such as adrenaline used for the treatment of hypotension, shock, cardiac failure, asthma or allergies
- lithium, a drug used to treat certain mental disorders.



HOW SHOULD YOU TAKE 'COZAAR'-COMP?

'Cozaar'-Comp should be taken by mouth.

You must keep taking 'Cozaar'-Comp every day and exactly as your doctor has told you. It is important that you take 'Cozaar'-Comp for as long as your doctor prescribes, in order to keep your blood pressure controlled.



Usually patients will start combination therapy with losartan and hydrochlorothiazide with a dose of 50 mg losartan potassium and 12.5 mg hydrochlorothiazide daily. If your blood pressure is not controlled with this, your doctor will normally prescribe one tablet of 'Cozaar'-Comp daily (100 mg losartan potassium and 25 mg hydrochlorothiazide).

If you are aged over 75 years you should check with your doctor before taking your tablets.

You can take 'Cozaar'-Comp with or without food. It is recommended that you take your tablet at the same time each day.

WHAT IF YOU FORGET TO TAKE A TABLET OR TAKE TOO MANY?

Try to take 'Cozaar'-Comp daily as prescribed. However, if you miss a dose, just carry on with the next dose as normal. Do not take an extra tablet to make up.

If you take too many tablets by mistake, contact your doctor immediately.

WHAT UNWANTED EFFECTS COULD 'COZAAR'-COMP HAVE?

Any medicine may have unintended or undesirable effects, so-called side effects. They are generally mild and do not normally require treatment to be interrupted. Most patients do not have side effects from 'Cozaar'-Comp; however, some patients, may experience, cough, dizziness, diarrhoea, and rarely hepatitis (inflammation of the liver, symptoms of which are yellowing of the whites of the eyes and skin and flu-like symptoms).

Some patients may present with hives. Rarely patients have reported developing an allergic reaction involving swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing; and/or inflammation of blood vessels including inflammation of small veins, causing hard, purple blotches on the skin. If you develop any of these symptoms stop taking 'Cozaar'-Comp and contact your doctor immediately.

Additional side effects that have been seen with either losartan or hydrochlorothiazide alone (the two active ingredients in 'Cozaar'-Comp), and may be potential side effects with 'Cozaar'-Comp, are:

Losartan: Few patients have reported a rapid lowering in blood pressure (symptoms of which may be lightheadedness or dizziness, particularly when standing up); itching; rash; muscle pain; migraine; liver problems (signs of which may be yellowing of the eyes and skin and flu-like symptoms), or anaemia (symptoms may be tiredness or shortness of breath caused by the number of red blood cells or amount of haemoglobin in the blood being below normal) which are usually detected by blood tests.

Hydrochlorothiazide: loss of appetite; stomach upsets; nausea; vomiting; stomach cramps; constipation; jaundice seen as yellowing of the skin and/or whites of the eyes; an inflamed pancreas marked by pain in the abdomen and back; swelling of the salivary glands; vertigo (spinning sensation); pins and needles; headache; visual changes which can make objects appear yellow; anaemia marked by unusual tiredness and a loss of colour in the linings of the eyes and skin; other blood disorders which can result in fever; sore throat or prolonged bleeding after injury; increased skin sensitivity to sunlight; purplish or reddish-brown marks on the skin; fever; hives or a nettle-like rash, inflammation of blood vessels; breathing problems due to inflamed or swollen lungs; allergic reactions marked by rash, hives, or difficulties in breathing or swallowing; blistering or peeling of the skin, mouth, eyes or genitals; changes in the levels of certain chemicals in the blood and urine which are usually detected by blood and urine tests; kidney problems; muscle spasm; weakness; restlessness; blurred vision.

If you notice any of these effects, or if you have any other unusual symptoms or feelings, contact your doctor immediately.

It will help if you make a note of what you experienced, when it started and how long it lasted.

HOW SHOULD YOUR TABLETS BE KEPT?

Keep your tablets out of the reach of children.

No special storage conditions are required for this medicine.

Do not put the tablets into another container, they might get mixed up. Do not remove the tablets from the blister pack or open the blister pack until you are ready to take the medicine.



Do not take the tablets past the expiry date, which is clearly marked on the pack.

REMEMBER: This medicine is for you. Do not share it with anyone else. It may not suit them.

This leaflet was revised in May 2005.

HOW CAN YOU OBTAIN MORE INFORMATION ABOUT 'COZAAR'-COMP?

This leaflet gives you the most important patient information about 'Cozaar'-Comp. If you have any questions after you have read it, ask your doctor or pharmacist, who may give you further information.

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