PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

COZAAR® COMP 50/12,5 Tablets contain 50 mg losartan potassium and 12,5 mg hydrochlorothiazide.

COZAAR® COMP 100/12,5 Tablets contain 100 mg losartan potassium and 12,5 mg hydrochlorothiazide.

Read all of this leaflet carefully before you start taking COZAAR COMP

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- COZAAR COMP 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.

1. WHAT COZAAR COMP CONTAINS

COZAAR COMP 50,12,5 (losartan potassium-hydrochlorothiazide) are film-coated tablets containing 50 mg of losartan potassium and 12,5 mg of hydrochlorothiazide as the active ingredients.

Inactive ingredients: carnauba wax, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, quinolone yellow aluminium lake, titanium dioxide.

COZAAR COMP 100/12,5 (losartan potassium-hydrochlorothiazide) are film-coated tablets containing 100 mg of losartan potassium and 12,5 mg of hydrochlorothiazide as the active ingredients.
Inactive ingredients: carnauba wax, hydroxypropyl cellulose, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pregelatinised maize starch, titanium dioxide.

Although COZAAR COMP 50/12,5 and COZAAR COMP 100/12,5 contain a very small amount of potassium, it cannot replace potassium supplements. If your doctor has prescribed potassium supplements, continue to follow his advice.

2. WHAT COZAAR COMP IS USED FOR

COZAAR COMP is a combination of angiotensin II receptor antagonist (losartan) and a diuretic (hydrochlorothiazide). Losartan and hydrochlorothiazide work together to lower high blood pressure.

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

3. BEFORE YOU TAKE COZAAR COMP

Do not take COZAAR COMP:

- if you are hypersensitive (allergic) to any of its ingredients (see **WHAT COZAAR COMP CONTAINS**).
- if you have previously been treated with a medication in the same group of medicines as COZAAR COMP (angiotensin receptor antagonists) or with a medication in the group of medicines known as ACE inhibitors and have had allergic reactions with swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.

- if you have or have had angioedema (swelling of the face, lips, mouth, tongue or throat with or without difficulty in swallowing or breathing) while taking COZAAR COMP or a similar medicine.
- 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 severe kidney disease.
- if you have narrowing of the blood vessels to both kidneys or to a single kidney.
- if you have aortic valve stenosis, a narrowing of the aortic valve.
- if you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- if you have porphyria.
- Thiazide water tablets in (fixed dose) combination with COZAAR COMP should not be given to patients with Addison's disease. This therapy should also not be used in patients with severe kidney disease or patients not passing urine, and in patients who show allergy to other sulphonamide-derived medicines (ask your doctor if you are not sure what sulphonamide-derived medicines are).
- Lithium therapy (a medicine used to treat a certain kind of depression): Concomitant administration with COZAAR COMP may lead to toxic blood concentrations of lithium.
- if you are pregnant or breastfeeding (see **Pregnancy and Breastfeeding**).
- if you have liver disease.
- if you are taking a medicine called aliskiren to reduce blood pressure.

Take special care with COZAAR COMP

- If you have or have had medical problems, any allergies, or if you have recently suffered from excessive vomiting or diarrhoea.

- If you have liver or kidney problems, gout, diabetes, lupus erythematosus or if you are being treated with diuretics (water tablets). In these cases, your doctor may need to adjust the dose of your medication.
- If you are taking other medicines that may increase serum potassium (see **Taking other medicines with COZAAR COMP**).
- Before surgery and anaesthesia (even at the dentist's office), 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.

Use in children

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

Taking COZAAR COMP with food and drink

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

Pregnancy and Breastfeeding

You should not use COZAAR COMP if you are pregnant or breastfeeding your baby.

The use of COZAAR COMP while you are pregnant or breastfeeding is contraindicated. COZAAR COMP 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 COMP tell your doctor right away.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking COZAAR COMP.

Driving and using machinery

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.

Important Information about some of the ingredients of COZAAR COMP

COZAAR COMP contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking COZAAR COMP.

Taking other medicines with COZAAR COMP

You should tell your doctor about all medicines that you are taking or plan to take, including those obtained without a prescription. It is especially important for your doctor to know if you are taking potassium supplements, potassium sparing agents, salt substitutes containing potassium or other drugs that may increase serum potassium (e.g. trimethoprim-containing products), other medicines to reduce blood pressure, other diuretics (water tablets), medications to treat diabetes including insulin, muscle relaxants, steroids or certain pain and arthritis medicines or lithium. Sedatives, tranquilisers, narcotics, alcohol and analgesics may increase the blood pressure-lowering effect of COZAAR COMP, so tell your doctor if you take any of these medicines.

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

4. HOW TO TAKE COZAAR COMP

Take COZAAR COMP every day, exactly as your doctor has instructed. It is important to continue taking COZAAR COMP for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

The usual dose of COZAAR COMP for most patients is one tablet of COZAAR COMP per day.

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

If you take more COZAAR COMP than you should

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

If you forget to take COZAAR COMP

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

5. POSSIBLE SIDE EFFECTS

COZAAR COMP can have side effects.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking COZAAR COMP, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking COZAAR COMP and tell your doctor immediately or go to the casualty department at your nearest hospital:

- allergic reaction involving swelling of the face, lips, throat and/or tongue
- rash
- hives.

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

Tell your doctor if you notice any of the following:

- nausea
- vomiting
- cramping
- diarrhoea
- constipation
- headache
- weakness
- fatigue
- dizziness
- taste disturbances
- dizziness or light headedness due to a sudden drop in blood pressure when standing up quickly
- transient blurred vision
- increased sensitivity of the skin to the sun.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF COZAAR COMP

Do not use this medicine after the month and year following EXP.: on the container. Return all unused medicine to your pharmacist.

Store COZAAR COMP at or below 30 °C.

Keep blister in carton until required for use. Protect from moisture.

Store all medicines out of reach of children.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

7. PRESENTATION OF COZAAR COMP

COZAAR COMP 50/12,5 is supplied in white, opaque PVC/PE/PVDC blisters with aluminium foil lidding in cartons containing 30 tablets.

COZAAR COMP 100/12,5 is supplied in white, opaque PVC/PE/PVDC blisters with aluminium foil lidding in cartons containing 30 tablets.

8. IDENTIFICATION OF COZAAR COMP

COZAAR COMP 50/12,5 Tablets are yellow oval shaped, film coated tablets, with 717 on one side and scored on the other side.

COZAAR COMP 100/12,5 Tablets are white, oval-shaped, film-coated tablets with 745 on one side and plain on the other side.

9. REGISTRATION NUMBERS

COZAAR COMP 50/12,5: 30/7.1.3/0284

COZAAR COMP 100/12,5: 46/7.1.3/0865

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

Date of registration:

COZAAR COMP 50/12,5: 08 April 1997

COZAAR COMP 100/12,5: 25 November 2016

Date of the most recent revision: 25 November 2016 (SR-PIN: 10 August 2018)

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