### Package leaflet: Information for the user

### COZAAR® 100mg film-coated tablets Losartan potassium

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

## What is in this leaflet

- What COZAAR is and what it is used for
- What you need to know before you take COZAAR
- How to take COZAAR
- 4. Possible side effects
- How to store COZAAR
- Contents of the pack and other information

Losartan (COZAAR) belongs to a group of medicines known as angiotensin-II receptor antagonists. Angiotensin-II is a substance produced in the body which binds to receptors in blood vessels, causing them to tighten. This results in an increase in blood pressure. Losartan prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Losartan slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

### COZAAR is used

- to treat patients with high blood pressure (hypertension) in adults and in children and adolescents 6 - 18 years of age
- to protect the kidney in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria  $\geq 0.5\, g$  per day (a condition in which urine contains an abnormal amount of protein).
- to treat patients with chronic heart failure when therapy with specific medicines called angiotensin-converting-enzyme inhibitors (ACE inhibitors, medicine used to lower high blood pressure) is not considered suitable by your doctor. If your heart failure has been stabilised with an ACE inhibitor you should not be switched to losartan.
- in patients with high blood pressure and a thickening of the left ventricle, COZAAR has been shown to decrease the risk of stroke ("LIFE indication").

## 2. What you need to know before you take COZAAR

### Do not take COZAAR:

- if you are allergic to losartan or to any of the other ingredients of this medicine (listed in section 6),
- if you are more than 3 months pregnant (It is also better to avoid COZAAR in early pregnancy - see Pregnancy),
- if your liver function is severely impaired,
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren

## Warnings and precautions

Talk to your doctor, pharmacist, or nurse before taking COZAAR.

You must tell your doctor if you think you are (or might become) pregnant. COZAAR is not recommended in early pregnancy, and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

# It is important to tell your doctor before taking COZAAR:

- if you have had a history of angioedema (swelling of the face, lips, throat, and/or tongue) (see also section 4 'Possible side effects'), if you suffer from excessive vomiting or diarrhoea leading to an extreme loss
- of fluid and/or salt in your body, if you receive diuretics (medicines that increase the amount of water that you
- pass out through your kidneys) or are under dietary salt restriction leading to an extreme loss of fluid and salt in your body (see section 3 'Dosage in special if you are known to have narrowing or blockage of the blood vessels leading
- to your kidneys or if you have received a kidney transplant recently,
- if your liver function is impaired (see sections 2 "Do not take COZAAR" and 3 'Dosage in special patient groups'),
- if you suffer from heart failure with or without renal impairment or concomitant severe life threatening cardiac arrhythmias. Special caution is necessary when you are treated with a  $\beta$ -blocker concomitantly,
- if you have problems with your heart valves or heart muscle, if you suffer from coronary heart disease (caused by a reduced blood flow in the blood vessels of the heart) or from cerebrovascular disease (caused by a reduced blood circulation in the brain),
- if you suffer from primary hyperaldosteronism (a syndrome associated with increased secretion of the hormone aldosterone by the adrenal gland, caused by an abnormality within the gland), if you are taking any of the following medicines used to treat high blood
- - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskiren

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals

See also information under the heading "Do not take COZAAR". if you are taking other medications that may increase serum potassium (see section 2 "Other medicines and COZAAR").

# Children and adolescents

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

COZAAR is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups. COZAAR is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

# Other medicines and COZAAR

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

Tell your doctor if you are taking potassium supplements, potassium-containing salt substitutes, potassium-sparing medicines such as certain diuretics (amiloride, triamteren, spironolactone), or other medicines that may increase serum potassium (e.g., heparin, trimethoprim-containing medicines), as the combination with COZAAR is not advisable. Take particular care if you are taking the following medicines while under treatment

with COZAAR: other blood pressure lowering medicines as they may additionally reduce

- your blood pressure. Blood pressure may also be lowered by one of the following drugs/ class of drugs: tricyclic antidepressants, antipsychotics, baclofene, amifostine, non-steroidal anti-inflammatory drugs such as indomethacin, including
- cox-2-inhibitors (medicines that reduce inflammation, and can be used to help relieve pain) as they may reduce the blood pressure lowering effect of losartan. Your doctor may need to change your dose and/or to take other precautions

If you are taking an ACE-inhibitor or aliskiren (see also information under the headings "Do not take COZAAR" and "Warnings and precautions"). If your kidney function is impaired, the concomitant use of these medicines may

Lithium containing medicines should not be taken in combination with losartan

without close supervision by your doctor. Special precautionary measures (e.g. blood tests) may be appropriate.

# COZAAR with food and drink

COZAAR may be taken with or without food. Pregnancy and breast-feeding

lead to a worsening of the kidney function.

## Pregnancy You must tell your doctor if you think you are (or might become) pregnant. Your

doctor will normally advise you to stop taking COZAAR before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of COZAAR. COZAAR is not recommended in early pregnancy, and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Tell your doctor if you are breast-feeding or about to start breast-feeding. COZAAR is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed. Especially if your baby is a new-born, or born prematurely. Ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines** No studies on the effects on the ability to drive and use machines have been

COZAAR is unlikely to affect your ability to drive or use machines. However, as with many other medicines used to treat high blood pressure, losartan may

cause dizziness or drowsiness in some people. If you experience dizziness or drowsiness, you should consult your doctor before attempting such activities. **COZAAR** contains lactose COZAAR contains lactose monohydrate. If you have been told by your doctor

# that you have an intolerance to some sugars, contact your doctor before taking

3. How to take COZAAR

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. 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 Adult patients with High Blood Pressure Treatment usually starts with 50 mg losartan (one tablet COZAAR 50 mg) once a day. The maximal blood pressure lowering effect should be reached 3-6 weeks after beginning treatment. In some patients the dose may later be increased to 100 mg

losartan (two tablets COZAAR 50 mg or one tablet of COZAAR 100 mg) once daily. If you have the impression that the effect of losartan is too strong or too weak, please talk to your doctor or pharmacist.

# Use in children and adolescents

been shown to work in this age group.

Children below 6 years of age COZAAR is not recommended for use in children under 6 years old, as it has not

### Children aged 6-18 years old

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7 mg of losartan per kg of body weight administered once a day (up to 25 mg of COZAAR). The doctor may increase the dose if blood pressure is not controlled.

Other form(s) of this medicine may be more suitable for children; ask your doctor

Adult patients with high blood pressure and Type 2 diabetes
Treatment usually starts with 50 mg losartan (one tablet COZAAR 50 mg) once a day. The dose may later be increased to 100 mg losartan (two tablets COZAAR 50 mg or one tablet of COZAAR 100 mg) once daily depending on your

Losartan may be administered with other blood pressure lowering medicines (e.g. diuretics, calcium channel blockers, alpha- or beta-blockers, and centrally acting agents) as well as with insulin and other commonly used medicines that decrease the level of glucose in the blood (e.g. sulfonylureas, glitazones and glucosidase inhibitors).

## Dosage in special patient groups

The doctor may advise a lower dose, especially when starting treatment in certain patients such as those treated with diuretics in high doses, in patients with liver impairment, or in patients over the age of 75 years. The use of losartan is not recommended in patients with severe hepatic impairment (see section "Do not take COZAAR")

### Administration

take your daily dose at about the same time each day. It is important that you continue to take COZAAR until your doctor tells you otherwise

## If you take more COZAAR than you should

If you accidentally take too many tablets, contact your doctor immediately. Symptoms of overdose are low blood pressure, increased heartbeat, possibly decreased heartbeat.

a double dose to make up for a forgotten tablet. If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody

A severe allergic reaction (rash, itching, swelling of the face, lips, mouth or throat that may cause difficulty in swallowing or breathing).

This is a serious but rare side effect, which affects more than 1 out of 10,000 patients

The following side effects have been reported with COZAAR:

Common (may affect up to 1 in 10 people):

- low blood pressure (especially after excessive loss of water from the body within blood vessels e.g. in patients with severe heart failure or under treatment with high dose diuretics),
- dose-related orthostatic effects such as lowering of blood pressure appearing when rising from a lying or sitting position,
- debility,

- too little sugar in the blood (hypoglycaemia), too much potassium in the blood (hyperkalaemia),
- changes in kidney function including kidney failure, reduced number of red blood cells (anaemia),
- increase in blood urea, serum creatinine and serum potassium in patients with heart failure

Uncommon (may affect up to 1 in 100 people):
• somnolence,

- - sleep disorders.
  - feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris), shortness of breath (dyspnoea),

- nausea,
- itching (pruritus),
- rash,
- purpura), numbness or tingling sensation (paraesthesia),
- and heartbeat (atrial fibrillation),
- brain attack (stroke), inflammation of the liver (hepatitis), elevated blood alanine aminotransferase (ALT) levels, usually resolved upon

- migraine, liver function abnormalities,
- muscle and joint pain,
- back pain and urinary tract infection, increased sensitivity to the sun (photosensitivity), unexplained muscle pain with dark (tea-coloured) urine (rhabdomyolysis),
- inflammation of the pancreas (pancreatitis).
- low levels of sodium in the blood (hyponatraemia), depression.
- ringing, buzzing, roaring, or clicking in the ears (tinnitus), disturbed taste (dysgeusia).

Side effects in children are similar to those seen in adults.

Keep this medicine out of the sight and reach of children.

help provide more information on the safety of this medicine.

pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

# What COZAAR contains

The active substance is losartan potassium

5. How to store COZAAR

Each COZAAR 100 mg tablet contains 100 mg of losartan potassium. The other ingredients are microcrystalline cellulose (E460), lactose monohydrate,

pregelatinised maize starch, magnesium stearate (E572), hyprolose (E463), hypromellose (E464).

The COZAAR 100 mg tablets also contain carnauba wax (E903) and titanium

dioxide (E171). What COZAAR looks like and contents of the pack

## of losartan potassium. COZAAR is supplied in the following pack sizes:

COZAAR 100 mg - PVC/PE/PVDC blister packages with aluminium foil lidding in packs of 7, 10, 14, 15, 20, 28, 30(3x10), 50, 56, 84, 90, 98 or 280 tablets and unit-dose packages of 28, 56 and 98 tablets for

Not all pack sizes may be marketed. Marketing Authorisation Holder and RELEASE SITE

The Netherlands Manufacture

Merck Sharp & Dohme Ltd. Shotton Lane, Cramlington Northumberland NE23 3JU

# United Kingdom

- (THIS IS A MEDICAMENT)
  - Medicament is a product which affects your health, and its consumption
  - instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are experts in medicine, its benefits
    - and risks. Do not by yourself interrupt the period of treatment prescribed for you.
    - Do not repeat the same prescription without consulting your doctor. Keep medicament out of reach of children
    - Union of Arab Pharmacists

The tablets should be swallowed whole with a glass of water. You should try to

If you experience the following, stop taking losartan tablets and tell your doctor

but fewer than 1 out of 1,000 patients. You may need urgent medical attention or hospitalisation.

- diarrhoea,
- localised swelling (oedema),
- inflammation of blood vessels (vasculitis including Henoch-Schönlein
- irregular
- discontinuation of treatment.
- flu-like symptoms.

- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can

Do not use this medicine after the expiry date which is stated on the carton or the bottle label. The expiry date refers to the last day of that month. Cozaar 100mg: Store below 30 ° C in the closed original package protected from

6. Contents of the pack and other information

COZAAR 100 mg contains potassium in the following amount: 8.48 mg (0.216 mEq).

COZAAR 100 mg is supplied as unscored film-coated tablets containing 100 mg

hospital use. HDPE bottles of 100 tablets.

Merck Sharp & Dohme BV Waarderweg 39 2031 BN Haarlem

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- contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use, and the

  - Council of Arab Health Ministers

- If you forget to take COZAAR If you accidentally miss a daily dose, just take the next dose as normal. Do not take

immediately or go to the casualty department of your nearest hospital

- - headache,
  - abdominal pain, obstipation,
- vomiting, hives (urticaria),
- Rare (may affect up to 1 in 1,000 people): angioedema.
  - fainting (syncope), very rapid ar
- Not known (frequency cannot be estimated from the available data):

  reduced number of thrombocytes,
- generally feeling unwell (malaise),
- Reporting of side effects