

## 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
- Possible side effects
- How to store Cozaar
- Contents of the pack and other information

#### 1. What Cozaar is and what it is used for

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 patient groups'),
- 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 pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskirenYour 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**'.

##### 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.

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,
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamteren, spironolactone] or heparin),
- 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 lead to a worsening of the kidney function.

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

###### 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.

###### Breast-feeding

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 newborn, 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 performed. 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 this medicine.

#### 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 50mg losartan (one tablet Cozaar 50mg) 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 100mg losartan (two tablets Cozaar 50mg or one tablet of Cozaar 100mg) 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

###### Children below 6 years of age

Cozaar is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

###### Children aged 6-18 years old

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7mg of losartan per kg of body weight administered once a day (up to 25mg 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 or pharmacist.

##### Adult patients with high blood pressure and Type 2 diabetes

Treatment usually starts with 50mg losartan (one tablet Cozaar 50mg) once a day. The dose may later be increased to 100mg losartan (two tablets Cozaar 50mg or one tablet of Cozaar 100mg) once daily depending on your blood pressure response. 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).

##### Adult patients with Heart Failure

Treatment usually starts with 12.5mg losartan (one tablet Cozaar 12.5mg) once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5mg daily during the first week, 25mg daily during the second week, 50mg daily during the third week, 100mg daily during the fourth week, 150mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150mg losartan (for example, three tablets of Cozaar 50mg or one tablet each of Cozaar 100mg and Cozaar 50mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

##### 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

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

##### If you forget to take Cozaar

If you accidentally miss a daily dose, just take the next dose as normal. Do not take 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 gets them.

If you experience the following, stop taking losartan tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

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

The following side effects have been reported with Cozaar:

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

- dizziness,
- 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,
- fatigue,
- 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,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- shortness of breath (dyspnoea),
- abdominal pain,
- obstipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema),
- cough.

*Rare (may affect up to 1 in 1,000 people):*

- hypersensitivity
- angioedema
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (atrial fibrillation),
- brain attack (stroke),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

*Not known (frequency cannot be estimated from the available data):*

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

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

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2  
Tel: +353 1 6764971 Fax: +353 1 6762517  
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Cozaar

Keep this medicine out of the sight and reach of children. Store Cozaar in the original package in order to protect from light and moisture.

Do not use this medicine after the expiry date which is stated on the blister label. The expiry date refers to the last day of that month.

Do not open the blister pack until you are ready to take the medicine.

If your tablets appear discoloured, damaged or show any other signs of deterioration, take them back to your pharmacist who will advise you.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

#### 6. Contents of the pack and other information

##### What Cozaar contains

The active substance is losartan potassium. Each tablet contains 91.6mg of losartan as 100mg losartan potassium.

The other ingredients are microcrystalline cellulose (E460), lactose monohydrate, pregelatinized maize starch, magnesium stearate (E572), hypromellose (E463), hypromellose (E464), carnauba wax (E903) and titanium dioxide (E171).

Cozaar 100mg contains 8.48mg (0.216 mEq) potassium.

##### What COZAAR looks like and contents of the pack

Cozaar are white, teardrop-shaped, film-coated tablet marked '960' on one side and plain on the reverse.

Cozaar is available in blister packs containing 28 tablets.

##### Manufacturer

Manufactured by: Merck Sharp & Dohme BV – Holland, Waarderweg 39, 2031 BN, 2003 PC Haarlem, Netherlands

or

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

or

Merck Sharp & Dohme SpA, Via Emilia, 21, 17100 Pavia, Italy

or

Frosst Iberica SA, Via Complutense 140, 28805,

Alcala de Henares, Madrid, Spain

Procured from within the EU and Repackaged by:

Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/5/2

#### This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	COSAAR Filmtabletten
Belgium, Czech Republic, Finland, Luxembourg, Slovakia	COZAAR
Belgium, Luxembourg	LOORTAN
Bulgaria, Cyprus, Denmark, Greece, Hungary, Poland, Iceland, Norway	COZAAR
Estonia	COZAAR
France, Ireland, Latvia, Malta, United Kingdom	COZAAR film-coated tablets
Germany	LORZAAR, LORZAAR PROTECT, PINZAAR filmtabletten
Italy	LORTAAN, NEO-LOTAN, LOSAPREX compresse revistite con film
Lithuania	COZAAR (Losartan)
Netherlands	COZAAR
Portugal	COZAAR, COZAAR IC, LORTAAN IC, LORTAAN
Slovenia	COZAAR filmsko obložene tablete
Spain	COZAAR
Sweden	COZAAR filmdragerade tabletter

Leaflet issue and revision date (ref): 19.05.15

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#### 1. What Cozaar is and what it is used for

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 patient groups'),
- 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 pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskirenYour 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**'.

##### 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.

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,
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamteren, spironolactone] or heparin),
- 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 lead to a worsening of the kidney function.

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

###### 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.

###### Breast-feeding

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 newborn, 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 performed. 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 this medicine.

#### 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 50mg losartan (one tablet Cozaar 50mg) 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 100mg losartan (two tablets Cozaar 50mg or one tablet of Cozaar 100mg) 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

###### Children below 6 years of age

Cozaar is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

###### Children aged 6-18 years old

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7mg of losartan per kg of body weight administered once a day (up to 25mg 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 or pharmacist.

##### Adult patients with high blood pressure and Type 2 diabetes

Treatment usually starts with 50mg losartan (one tablet Cozaar 50mg) once a day. The dose may later be increased to 100mg losartan (two tablets Cozaar 50mg or one tablet of Cozaar 100mg) once daily depending on your blood pressure response. 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).

##### Adult patients with Heart Failure

Treatment usually starts with 12.5mg losartan (one tablet Cozaar 12.5mg) once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5mg daily during the first week, 25mg daily during the second week, 50mg daily during the third week, 100mg daily during the fourth week, 150mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150mg losartan (for example, three tablets of Cozaar 50mg or one tablet each of Cozaar 100mg and Cozaar 50mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

##### 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

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

##### If you forget to take Cozaar

If you accidentally miss a daily dose, just take the next dose as normal. Do not take 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 gets them.

If you experience the following, stop taking losartan tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

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

The following side effects have been reported with Cozaar:

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

- dizziness,
- 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,
- fatigue,
- 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,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- shortness of breath (dyspnoea),
- abdominal pain,
- obstipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema),
- cough.

*Rare (may affect up to 1 in 1,000 people):*

- hypersensitivity
- angiooedema
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (atrial fibrillation),
- brain attack (stroke),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

*Not known (frequency cannot be estimated from the available data):*

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

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

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2  
Tel: +353 1 6764971 Fax: +353 1 6762517  
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Cozaar

Keep your tablets out of the sight and reach of children. Store in the original package in order to protect from light and moisture.

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

Do not take the tablets past the expiry date (EXP), which is clearly marked on the carton and blister label. The expiry date refers to the last day of that month.

If your tablets appear discoloured, damaged or show any other signs of deterioration, take them back to your pharmacist who will advise you.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What Cozaar contains

**Active ingredients:** The active ingredient in Cozaar is losartan potassium. Each tablet contains 91.6mg of losartan as 100mg losartan potassium.

**Other ingredients:** microcrystalline cellulose (E460), lactose monohydrate, pregelatinised maize starch, magnesium stearate (E572), hypromellose (E463) and hypromellose (E464). The printing ink contains carnauba wax (E903) and titanium dioxide (E171).

Cozaar 100mg contains 8.48mg (0.216 mEq) of potassium.

##### What Cozaar looks like and contents of the pack

Cozaar are white, teardrop-shaped, film-coated tablets marked '960' on one side and plain on the reverse.

Cozaar Tablets are supplied in blister packs containing 28 tablets.

Manufactured by: Merck Sharp & Dohme Limited, Shotton Lane, Cramlington, Northumberland, UK.

Procured from within the EU and Repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, DN3 1QR, UK.

PPA holder: Imbat Ltd., Santry, Dublin 9.

Distributed by: Eurodrug Ltd., Santry, Dublin 9.

PPA No: 1151/5/2

##### This medicinal product is authorised in the Member States of the EEA under the following names:

Austria	COSAAR Filmtabletten
Belgium, Czech Republic, Finland, Luxembourg, Slovakia	COZAAR
Belgium, Luxembourg	LOORTAN
Bulgaria, Cyprus, Denmark, Greece, Hungary, Poland, Iceland, Norway	COZAAR
Estonia	COZAAR
France, Ireland, Latvia, Malta, United Kingdom	COZAAR film-coated tablets
Germany	LORZAAR, LORZAAR PROTECT, PINZAAR filmtabletten
Italy	LORTAAN, NEO-LOTAN, LOSAPREX compresse revistite con film
Lithuania	COZAAR (Losartan)
Netherlands	COZAAR
Portugal	COZAAR, COZAAR IC, LORTAAN IC, LORTAAN
Slovenia	COZAAR filmsko obložene tablete
Spain	COZAAR
Sweden	COZAAR filmdragerade tabletter

Leaflet issue and revision date (ref): 19.05.15

Cozaar<sup>®</sup> is a registered trademark of Merck Sharp & Dohme Corp.

## 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
- Possible side effects
- How to store Cozaar
- Contents of the pack and other information

### 1. What Cozaar is and what it is used for

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 patient groups'),
- 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 pressure:
  - an ACE-inhibitor (for example enalapril, lisinopril, ramipril), in particular if you have diabetes-related kidney problems.
  - aliskirenYour 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**'.

#### 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.

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,
- medicines which retain potassium or may increase potassium levels (e.g. potassium supplements, potassium-containing salt substitutes or potassium-sparing medicines such as certain diuretics [amiloride, triamteren, spironolactone] or heparin),
- 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 lead to a worsening of the kidney function.

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

##### 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.

##### Breast-feeding

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 newborn, 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 performed. 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 this medicine.

### 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 50mg losartan (one tablet Cozaar 50mg) 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 100mg losartan (two tablets Cozaar 50mg or one tablet of Cozaar 100mg) 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

##### Children below 6 years of age

Cozaar is not recommended for use in children under 6 years old, as it has not been shown to work in this age group.

##### Children aged 6-18 years old

The recommended starting dose in patients who weigh between 20 and 50 kg is 0.7mg of losartan per kg of body weight administered once a day (up to 25mg 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 or pharmacist.

##### Adult patients with high blood pressure and Type 2 diabetes

Treatment usually starts with 50mg losartan (one tablet Cozaar 50mg) once a day. The dose may later be increased to 100mg losartan (two tablets Cozaar 50mg or one tablet of Cozaar 100mg) once daily depending on your blood pressure response. 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).

##### Adult patients with Heart Failure

Treatment usually starts with 12.5mg losartan (one tablet Cozaar 12.5mg) once a day. Generally, the dose should be increased weekly step-by-step (i.e., 12.5mg daily during the first week, 25mg daily during the second week, 50mg daily during the third week, 100mg daily during the fourth week, 150mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150mg losartan (for example, three tablets of Cozaar 50mg or one tablet each of Cozaar 100mg and Cozaar 50mg) once daily may be used.

In the treatment of heart failure, losartan is usually combined with a diuretic (medicine that increases the amount of water that you pass out through your kidneys) and/or digitalis (medicine that helps to make the heart stronger and more efficient) and/or a beta-blocker.

#### 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

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

#### If you forget to take Cozaar

If you accidentally miss a daily dose, just take the next dose as normal. Do not take 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 gets them.

If you experience the following, stop taking losartan tablets and tell your doctor immediately or go to the casualty department of your nearest hospital:

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

The following side effects have been reported with Cozaar:

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

- dizziness,
- 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,
- fatigue,
- 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,
- headache,
- sleep disorders,
- feeling of increased heart rate (palpitations),
- severe chest pain (angina pectoris),
- shortness of breath (dyspnoea),
- abdominal pain,
- obstipation,
- diarrhoea,
- nausea,
- vomiting,
- hives (urticaria),
- itching (pruritus),
- rash,
- localised swelling (oedema),
- cough.

*Rare (may affect up to 1 in 1,000 people):*

- hypersensitivity
- angiooedema
- inflammation of blood vessels (vasculitis including Henoch-Schönlein purpura),
- numbness or tingling sensation (paraesthesia),
- fainting (syncope),
- very rapid and irregular heartbeat (atrial fibrillation),
- brain attack (stroke),
- inflammation of the liver (hepatitis),
- elevated blood alanine aminotransferase (ALT) levels, usually resolved upon discontinuation of treatment.

*Not known (frequency cannot be estimated from the available data):*

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

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

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRa Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2  
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By reporting side effects you can help provide more information on the safety of this medicine.

#### 5. How to store Cozaar

Keep your tablets out of the sight and reach of children. Store in the original package in order to protect from light and moisture.

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

Do not take the tablets past the expiry date (EXP), which is clearly marked on the carton and blister label. The expiry date refers to the last day of that month.

If your tablets appear discoloured, damaged or show any other signs of deterioration, take them back to your pharmacist who will advise you.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### 6. Contents of the pack and other information

##### What Cozaar contains

**Active ingredients:** The active ingredient in Cozaar Tablets is losartan potassium. Each tablet contains 91.6mg of losartan as 100mg losartan potassium.

**Other ingredients:** hypromellose E463; hypromellose E464; lactose monohydrate; magnesium stearate E572; microcrystalline cellulose E460; pregelatinised maize starch; titanium dioxide E171 and carnauba wax.  
Cozaar 100mg contains 8.48mg (0.216 mEq) of potassium.

##### What Cozaar looks like and contents of the pack

Cozaar are white, teardrop-shaped, film-coated tablets marked '960' on one side and plain on the reverse.

Cozaar Tablets are supplied in blister packs containing 28 tablets.

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Belgium, Luxembourg	LOORTAN
Bulgaria, Cyprus, Denmark, Greece, Hungary, Poland, Iceland, Norway	COZAAR
Estonia	COZAAR
France, Ireland, Latvia, Malta, United Kingdom	COZAAR film-coated tablets
Germany	LORZAAR, LORZAAR PROTECT, PINZAAR filmtabletten
Italy	LORTAAN, NEO-LOTAN, LOSAPREX compresse revistite con film
Lithuania	COZAAR (Losartan)
Netherlands	COZAAR
Portugal	COZAAR, COZAAR IC, LORTAAN IC, LORTAAN
Slovenia	COZAAR filmsko obložene tablete
Spain	COZAAR
Sweden	COZAAR filmdragerade tabletter

Leaflet issue and revision date (ref): 19.05.15

Cozaar® is a registered trademark of Merck Sharp & Dohme Corp