

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cosartal 50 mg Film-coated Tablets Cosartal 100 mg Film-coated Tablets Losartan Potassium

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

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Cosartal is and what it is used for**
- 2. What you need to know before you take Cosartal**
- 3. How to take Cosartal**
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1. What Cosartal is and what it is used for

Cosartal 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. Cosartal prevents the binding of angiotensin-II to these receptors, causing the blood vessels to relax which in turn lowers the blood pressure. Cosartal slows the decrease of kidney function in patients with high blood pressure and type 2 diabetes.

Cosartal 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 function in hypertensive type 2 diabetic patients with laboratory evidence of impaired renal function and proteinuria ≥ 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, Cosartal has been shown to decrease the risk of stroke (“LIFE indication”).

2. What you need to know before you take Cosartal

Do not take Cosartal:

- If you are allergic (hypersensitive) to losartan or any of the other ingredients of this medicine (listed in section 6).
- If your liver function is severely impaired.

- If you are more than 3 months pregnant. (It is also better to avoid Cosartal tablets in early pregnancy – see pregnancy section).
- 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 or pharmacist before taking Cosartal:

- 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 section 2 ‘Do not take Cosartal Film-coated Tablets’ and section 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 think you are (or might become) pregnant. Cosartal tablets are 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).
- 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.
 - 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 Cosartal.”

Children and adolescents

Cosartal film-coated tablets have been studied in children.

For more information, talk to your doctor.

Cosartal is not recommended for use in children suffering from kidney or liver problems, as limited data are available in these patient groups. Cosartal 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 Cosartal:

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 Cosartal:

- 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, baclofen, 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, triamterene, 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 lowering effect of losartan.

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.

Special caution is necessary if you are being treated concomitantly with another angiotensin-II receptor antagonist (such as valsartan or telmisartan) as the frequency of low blood pressure, fainting, increase in potassium levels and changes in kidney function may be increased.

Your doctor may need to change your dose and/or take other precautions:

- If you are taking an ACE-inhibitor or aliskiren (see also information under the headings “Do not take Cosartal” and “Warnings and precautions”).

Cosartal with food, drink and alcohol

Cosartal film-coated tablets may be taken with or without food.

Pregnancy, breast-feeding and fertility

If you are pregnant, or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Cosartal tablets before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Cosartal tablets.

Cosartal tablets are 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. Cosartal tablets are 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 newborn, or was born prematurely.

Driving and using machines

No studies on the effects on the ability to drive and use machines have been performed. Cosartal film-coated tablets are 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.

3. How to take Cosartal

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. Your doctor will decide on the appropriate dose of Cosartal, depending on your condition and whether you are taking other medicines.

It is important to continue taking Cosartal for as long as your doctor prescribes it in order to maintain smooth control of your blood pressure.

The recommended dose is:

Adults with high blood pressure

Treatment usually starts with 50 mg losartan 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 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

Cosartal 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 with high blood pressure

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 Cosartal). The doctor may increase the dose if blood pressure is not controlled.

Adults with high blood pressure and type 2 diabetes

Treatment usually starts with 50 mg losartan once a day. The dose may later be increased to 100 mg losartan once daily depending on your blood pressure response. Losartan tablets 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 12.5 mg losartan once a day (this dose cannot be achieved with Cosartal; there are other losartan potassium formulations available to achieve this dose. Please speak to your doctor, pharmacist or nurse). Generally, the dose should be increased weekly step-by-step (i.e., 12.5 mg daily during the first week, 25 mg daily during the second week, 50 mg daily during the third week, 100 mg daily during the fourth week, 150 mg daily during the fifth week) up to the maintenance dose as determined by your physician. A maximum dose of 150 mg losartan (for example, three tablets of Cosartal 50 mg or one tablet each of Cosartal 100 mg and Cosartal 50 mg) 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 Cosartal').

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 Cosartal until your doctor tells you otherwise.

The tablet can be divided into equal doses.

If you take more Cosartal than you should

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

If you forget to take Cosartal

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 stop taking Cosartal

It is important that you continue to take Cosartal until your doctor tells you otherwise.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

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 losartan:

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

- dizziness
- low blood pressure
- feeling or being weak (debility)
- tiredness (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
- 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

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

- sleepiness (somnolence)
- headache
- sleep disorders
- feeling of increased heart rate (palpitations)
- severe chest pain (angina pectoris)
- shortness of breath (dyspnoea)
- abdominal pain
- severe constipation (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-Schonlein 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 – increased risk of bleeding and bruising
- 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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 Cosartal

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

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

Do not store above 25°C.

Do not throw away 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 Cosartal contains

The active substance is losartan potassium.

Each Cosartal 50 mg film-coated tablet contains 50 mg of losartan potassium.

Each Cosartal 100 mg film-coated tablet contains 100 mg of losartan potassium.

The other ingredients are *tablet core*: mannitol, microcrystalline cellulose, croscarmellose sodium, povidone, magnesium stearate; *film-coat*: hypromellose, titanium dioxide (E171), talc, propylene glycol.

What Cosartal looks like and contents of the pack

Cosartal 50 mg: White, round biconvex, scored, coated tablets, marked 3 L.

Cosartal 100 mg: White, oval biconvex, scored, coated tablets, marked 4 L.

The tablets can be divided into equal halves.

PVC/PVDC/Al blister

Pack sizes: 5, 7, 10, 14, 15, 20, 21, 28, 30, 50, 56, 60, 84, 90, 98, 100, 120, 210, 280 or 500 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:

Balkanpharma - Dupnitsa AD, 3 Samokovsko Shosse Str., Dupnitsa 2600, Bulgaria.

PharmaPack International B.V., Bleiswijkseweg 51, 2712 PB Zoetermeer, The Netherlands

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