

Package Leaflet: Information for the user

Ropril 25 mg Tablets Ropril 50 mg Tablets Captopril

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 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 Ropril is and what it is used for
2. What you need to know before you take Ropril
3. How to take Ropril
4. Possible side effects
5. How to store Ropril
6. Contents of the pack and other information

1. What Ropril is and what it is used for

The name of this medicine is Ropril. Each tablet contains captopril (25mg or 50mg) as the active ingredient.

Ropril belongs to the group of medicines called Angiotensin Converting Enzyme (ACE) Inhibitors. ACE inhibitors work by helping to widen your blood vessels, which then make it easier for your heart to pump blood through them.

Ropril is used to treat high blood pressure and certain heart conditions. If high blood pressure is left uncontrolled it can increase the risk of heart disease or stroke. Ropril works by lowering your blood pressure which reduces this risk.

Ropril can also help people whose heart no longer pumps blood as well as it once did.

This condition is known as heart failure.

Ropril may also be used to treat patients who recently suffered a heart attack. A heart attack happens once one of the major blood vessels supplying blood to the heart muscle becomes blocked. This means that the heart does not receive the oxygen it needs and the heart muscle becomes damaged.

In addition, Ropril can be used for the treatment of kidney disease in patients with diabetes.

2. What you need to know before you take Ropril

Do not take Ropril tablets if you:

- Are more than 3 months **pregnant**. (It is also better to avoid Ropril in early pregnancy – see pregnancy section).
- Have ever had an **allergic** reaction to any ingredients of Ropril or to any other medicines, including other ACE inhibitors,
- Have ever had a **reaction** which included swelling of the hands, lips, face or tongue where the cause was unknown,

- Suffer from any **auto-immune disease** (e.g. rheumatoid arthritis, systemic lupus erythematosus or scleroderma).
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above affects you, or you are unsure if they do, tell your doctor who will be able to advise you.

Take special care with Ropril tablets

You must tell your doctor if you:

- Suffer from kidney disease,
- Suffer from liver disease,
- Are undergoing dialysis,
- Suffer from heart disease, in particular problems with the valves of the heart,
- Have diabetes,
- Have recently suffered from excessive vomiting or diarrhoea,
- Are receiving immuno-suppressant therapy.
- You think you are (or might become) pregnant. Ropril 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).
- If you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARBs) (also known as sartans – for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
 - aliskiren

Your doctor may need to 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 Ropril tablets if you:”.

If you are to have desensitisation treatment for wasp or bee stings you should tell the doctor who is treating you that you are taking Ropril.

If you are about to have treatment for the removal of cholesterol from your blood by a machine, (called LDL apheresis) you should tell your doctor you are taking Ropril.

Tell your doctor you are taking Ropril tablets before you have any blood or urine tests as Ropril tablets may interfere with the results of some tests.

Some Afro-Caribbean patients may require higher doses of Ropril to obtain an adequate reduction in blood pressure.

Taking Ropril with other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. It is especially important to tell your doctor if you are taking any of the following:

- Non steroidal anti-inflammatory painkillers **NSAIDs** (e.g. indomethacin, ibuprofen),
- **Immunosuppressants** (e.g. azathioprine and cyclophosphamide),
- Potassium supplements, salt substitutes containing potassium or any other medicines which can increase potassium in your body, e.g. (amiloride, spironolactone),
- **Water tablets** (diuretics),
- Medicines for **gout** (e.g. allopurinol),
- Medicines for **diabetes** (as the amount you need to use may have to be changed while taking Ropril),
- Medicines that cause dilation of the **blood vessels** (e.g. minoxidil, clonidine),
- Medicines to treat **mental health problems** including depression (such as lithium or amitriptyline),

- Any other medicines to treat **high blood pressure** (e.g. beta-blockers such as propranolol, atenolol or calcium channel blockers such as amlodipine, nifedipine),
- Any medicine that may be used during and after a **heart attack**.

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

If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings “Do not take Ropril tablets if you:” and “Take special care with Ropril tablets”).

Pregnancy and breastfeeding

Pregnancy

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

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Ropril. In the case of an older baby your doctor should advise you on the benefits and risks of taking Ropril whilst breast-feeding, compared with other treatments.

If you are due to have surgery

Before surgery and anaesthesia (even at the dentist) you should tell your doctor or dentist that you are taking Ropril as there may be a sudden fall in your blood pressure.

Taking with Food or Drink

Ropril can be taken with or without food.

Moderate amounts of alcohol will not affect Ropril, however, you should check with your doctor first to see if drinking is advisable for you.

Driving or operating machinery

Ropril can affect your ability to drive, usually when you first start taking your medicine or if your doctor changes your dose. If you do feel light-headed or dizzy when taking Ropril tablets, you should not drive or use machinery.

Important information about some of the ingredients in Ropril

Ropril contains 25mg to 50mg **lactose** which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Ropril

Take Ropril as instructed. Your pharmacist may also help if you are not sure.

The usual doses are:

For the treatment of high blood pressure

The usual starting dose is 12.5 - 25mg twice a day. Your doctor may gradually increase this dose to 100 - 150mg a day. You may also need to be given other medicines to lower your blood pressure.

Older patients and those with kidney problems may be given a lower starting dose.

In heart failure

The usual starting dose is 6.25 – 12.5mg two or three times a day. Your doctor may gradually increase this dose to a maximum of 150mg a day.

After a heart attack

The usual starting dose is 6.25mg, which will then be increased by your doctor to a maximum of 150mg a day.

For the treatment of diabetic patients with kidney disease

The usual dose is 75 - 100mg a day.

For children

The starting dose is 0.3mg/kg bodyweight, which may be increased gradually by the doctor.

For children with kidney problems, premature babies and newborn babies and infants

The starting dose should be 0.15mg/kg bodyweight.

Doctors sometimes prescribe different doses to the above and if this applies to you, you should discuss it with your doctor.

Sometimes patients may feel dizzy after taking the first one or two doses of Ropril. If this happens to you, lie down until these symptoms disappear.

You should try to take Ropril at about the same time each morning. It can be taken before, during or after meals

Even if you feel well continue to take Ropril until your doctor tells you otherwise.

If you take more Ropril than you should

If you or any one else takes too many tablets you should go to your nearest hospital emergency department or tell your doctor immediately. Take the carton and any remaining tablets you have with you.

If you forget to take Ropril

If you miss a dose do not worry. Just carry on taking your normal dose when the next one is due.

Do not take a double dose to make up for the one you missed.

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

4. Possible side effects

Like all medicines, Ropril may cause some unwanted side effects although not everybody gets them.

If you experience any of the following reactions **stop** taking Ropril and contact your doctor **immediately**:

- Swelling of the hands, face, lips or tongue.
- Difficulty in breathing,
- A sudden, unexpected rash or burning, red or peeling skin,
- Sore throat or fever,
- Severe dizziness or fainting,
- Severe stomach pain,
- Unusually fast or irregular heartbeat,
- Yellowing of the skin and/or eyes (jaundice).

Common side effects (affecting between 1 in 10 and 1 in 100 people)

- Dizziness,
- Itching,
- Rashes,
- Dry mouth,
- Sleep problems,
- Diarrhoea or constipation,

- Hair loss,
- Changes in the way things taste,
- Shortness of breath

- Dry, irritating cough,
- Upset stomach, sickness, abdominal pain.

Uncommon side effects (affecting between 1 in 100 and 1 in 1000 people)

- Fast, irregular, louder heartbeat,
- Chest pain,
- Low blood pressure,
- Reduced blood flow to the hands and feet (e.g. Raynaud syndrome),
- Flushing,
- Tiredness,
- Generally feeling unwell,
- Looking pale,
- Swelling of the eyes and lips (angioedema).

Rare side effects (affecting between 1 in 1000 and 1 in 10,000 people)

- Loss of appetite,
- Drowsiness,
- Headache,
- Pins and needles, numbness or tingling,
- Mouth ulcers,
- Kidney disorders or failure,
- Changes in frequency of passing urine.

Very rare side effects (affecting less than 1 in 10,000 people)

- Impaired liver function and raised liver enzymes,
- Confusion, depression, fainting,
- Mini-stroke,
- Blurred vision,
- Heart problems including heart attack, and chest infections,
- Inflammation of the pancreas,
- Runny nose,
- Swollen tongue,
- Impotence,
- Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals),
- Liver damage, inflammation of the liver or jaundice,
- Stomach ulcers,
- Muscle pain,
- Joint pain,
- Wheezing or difficulty breathing
- Rashes or skin reactions,
- Swelling of breast tissue in men,
- Fever,
- Sensitivity of the skin to light,
- Changes in levels of chemicals in the blood or lymphatic systems (e.g. potassium, sugars).

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately. It will help if you make a note of what you experienced, when it started and how long it lasted.

Reporting of side effects:

If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to the Pharmaceutical Services, Ministry of Health, CY-1475, www.moh.gov.cy/phs, Fax: + 35722608649. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Ropril

Store below 25°C. Protect from light and humidity.

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

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

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 Ropril contains

The active substance is captopril.

Each tablet of Ropril 25 contains 25mg captopril.

Each tablet of Ropril 50 contains 50mg captopril.

The other ingredients are: lactose, starch, microcrystalline cellulose, stearic acid.

What Ropril looks like and the contents of the pack

Ropril 25mg tablets are white, flat, round tablets, 8mm diameter in size, cross-scored on one side packed in Al/PVC blisters of 2x10 and 10x10 tablets.

Ropril 50mg tablets are white, concave, round tablets, 10mm diameter in size, scored on one side packed in Al/PVC blisters of 2x10 tablets.

Marketing Authorisation Holder and Manufacturer:

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