

PACKAGE LEAFLET: INFORMATION FOR THE USER

**NORMOPRIL 2.5 mg tablets**  
**NORMOPRIL 5 mg tablets**  
**NORMOPRIL 10 mg tablets**

Ramipril

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if their symptoms are the same as yours.
- 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.

**In this leaflet:**

1. What NORMOPRIL is and what it is used for
2. Before taking NORMOPRIL
3. How to take NORMOPRIL
4. Possible side effects
5. How to store NORMOPRIL
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**1. WHAT NORMOPRIL IS AND WHAT IT IS USED FOR**

NORMOPRIL contains a medicine called ramipril. This belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors).

NORMOPRIL works by:

- Decreasing your body's production of substances that could raise your blood pressure
- Making your blood vessels relax and widen
- Making it easier for your heart to pump blood around your body.

NORMOPRIL can be used:

- To treat high blood pressure (hypertension)
- To reduce the risk of you having a heart attack or stroke
- To reduce the risk or delay the worsening of kidney problems (whether or not you have diabetes)
- To treat your heart when it cannot pump enough blood to the rest of your body (heart failure)
- As treatment following heart attack (myocardial infarction) complicated with heart failure.

**2. BEFORE TAKING NORMOPRIL**

**Do not take NORMOPRIL:**

- If you are allergic (hypersensitive) to ramipril, any other ACE inhibitor medicine or any of the ingredients of NORMOPRIL listed in section 6.  
Signs of an allergic reaction may include a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you have ever had a serious allergic reaction called "angioedema". The signs include itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing.
- If you are having dialysis or any other type of blood filtration. Depending on the machine that is used, NORMOPRIL may not be suitable for you.
- If you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis).
- If you are **pregnant for more than three months** (It is recommended to avoid NORMOPRIL during the early months of pregnancy - see section below on "Pregnancy").
- If your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

Do not take NORMOPRIL if any of the above applies to you. If you are not sure, talk to your doctor before taking NORMOPRIL.

### **Take special care with NORMOPRIL**

Check with your doctor or pharmacist before taking your medicine:

- If you have heart, liver or kidney problems.
- If you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhoea, sweating more than usual, being on a low salt diet, taking diuretics for a long time or having had dialysis).
- If you are going to have treatment to reduce your allergy to bee or wasp stings (desensitization)
- If you are going to receive an anaesthetic. This may be given for an operation or any dental work. You may need to stop your NORMOPRIL treatment one day beforehand; ask your doctor for advice.
- If you have high amounts of potassium in your blood (shown in blood test results).
- If you have collagen vascular disease such as scleroderma or systemic lupus erythematosus.
- You must tell your doctor if you think that you are (or might become) pregnant. NORMOPRIL is not recommended in the first 3 months of pregnancy and may cause serious harm to your baby after 3 months of pregnancy, see section "Pregnancy".
- 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 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 NORMOPRIL."

#### *Children*

NORMOPRIL is not recommended for use in children and adolescents below 18 years of age because there is no information available in this population.

If any of the above apply to you (or you are not sure), talk to your doctor before taking NORMOPRIL.

### **Taking NORMOPRIL with other medicines**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (including herbal medicines). This is because NORMOPRIL can affect the way some other medicines work. Also some medicines can affect the way NORMOPRIL works.

Please tell your doctor if you are taking any of the following medicines. They can make NORMOPRIL work less well:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin).
- Medicines used for the treatment of low blood pressure, shock, heart failure, asthma or allergies such as ephedrine, noradrenaline or adrenaline. Your doctor will need to check your blood pressure.

Please tell your doctor if you are taking any of the following medicines. They can increase the chance of getting side effects if you take them with NORMOPRIL:

- Medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indometacin and aspirin).
- Medicines for cancer (chemotherapy).
- Medicines to stop the rejection of organs after a transplant such as ciclosporin.
- Diuretics (water tablets) such as furosemide.
- Medicines which can increase the amount of potassium in your blood such as spironolactone, triamterene, amiloride, potassium salts and heparin (for thinning blood).
- Steroid medicines for inflammation such as prednisolone.
- Allopurinol (used to lower the uric acid in your blood).
- Procainamide (for heart rhythm problems).
- 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 NORMOPRIL" and "Warnings and precautions").

Please tell your doctor if you are taking any of the following medicines. They may be affected by NORMOPRIL:

- Medicines for diabetes such as oral glucose lowering medicines and insulin. NORMOPRIL may lower your blood sugar amounts. Check your blood sugar amounts closely while taking NORMOPRIL.
- Lithium (for mental health problems). NORMOPRIL may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.

If any of the above apply to you (or you are not sure), talk to your doctor before taking NORMOPRIL.

#### **Taking NORMOPRIL with food and drink**

- Drinking alcohol with NORMOPRIL may make you feel dizzy or light-headed. If you are concerned about how much you can drink while you are taking NORMOPRIL, discuss this with your doctor as medicines used to reduce blood pressure and alcohol can have additive effects.
- NORMOPRIL may be taken with or without food.

#### **Pregnancy and breast-feeding**

##### **Pregnancy**

You must tell your doctor if you think that you are (or might become) pregnant. Your doctor will normally advise you to stop taking NORMOPRIL before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of NORMOPRIL. NORMOPRIL 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. NORMOPRIL is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you want to breast-feed, specially if your baby is new born, or was born prematurely.

Ask your doctor or pharmacist for advice before taking any medicine.

#### **Driving and using machines**

You may feel dizzy, while taking NORMOPRIL. This is more likely to happen when you start taking NORMOPRIL or start taking a higher dose. If this happens, do not drive or use any tools or machines.

### **3. HOW TO TAKE NORMOPRIL**

Always take NORMOPRIL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

#### **Taking this medicine**

- Take this medicine by mouth at the same time of the day each day.
- Swallow the tablets whole with liquid.
- Do not crush or chew the tablets.

#### **How much to take**

##### *Treatment of high blood pressure*

- The usual starting dose is 1.25 mg or 2.5 mg once daily.
- Your doctor will adjust the amount you take until your blood pressure is controlled.
- The maximum dose is 10 mg once daily.
- If you are already taking diuretics, your doctor may stop or reduce the amount of the diuretic you take before beginning treatment with NORMOPRIL.

##### *To reduce the risk of you having a heart attack or stroke*

- The usual starting dose is 2.5 mg once daily.
- Your doctor may then decide to increase the amount you take.
- The usual dose is 10 mg once daily.

##### *Treatment to reduce or delay the worsening of kidney problems*

- You may start with a dose of 1.25 mg or 2.5 mg once daily.
- Your doctor will adjust the amount you are taking.
- The usual dose is 5 mg or 10 mg once daily.

##### *Treatment of heart failure*

- The usual starting dose is 1.25 mg once daily.
- Your doctor will adjust the amount you take.
- The maximum dose is 10 mg daily. Two administrations per day are preferable.

##### *Treatment after you have had a heart attack*

- The usual starting dose is 1.25 mg once daily to 2.5 mg twice daily.
- Your doctor will adjust the amount you take.
- The usual dose is 10 mg daily. Two administrations per day are preferable.

### *Elderly*

Your doctor will reduce the initial dose and adjust your treatment more slowly.

### **If you take more NORMOPRIL than you should**

Tell your doctor or go to the nearest hospital casualty department straight away, taking this leaflet with you. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you. This is so the doctor knows what you have taken.

### **If you forgot to take NORMOPRIL**

- If you miss a dose, take your normal dose when it is next due.
- Do not take a double dose to make up for a forgotten dose.

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

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, NORMOPRIL can cause side effects, although not everybody gets them.

**Stop taking NORMOPRIL and see a doctor straight away, if you notice any of the following serious side effects - you may need urgent medical treatment:**

- Swelling of the face, lips or throat which make it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to NORMOPRIL.
- Severe skin reactions including rash, ulcers in your mouth, worsening of a pre-existing skin disease, reddening, blistering or detachment of skin (such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiform).

**Tell your doctor immediately if you experience:**

- Faster heart rate, uneven or forceful heartbeat (palpitations), chest pain, tightness in your chest or more serious problems including heart attack and stroke.
- Shortness of breath or a cough. These could be signs of lung problems.
- Bruising more easily, bleeding for longer than normal, any sign of bleeding (e.g. bleeding from the gums), purple spots blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin. These can be signs of blood or bone marrow problems.
- Severe stomach pain which may reach through to your back. This could be a sign of pancreatitis (inflammation of the pancreas).
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of your skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.

**Other side effects include:**

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

**Common** (affects less than 1 in 10 people)

- Headache or feeling tired
- Feeling dizzy. This is more likely to happen when you start taking NORMOPRIL or start taking a higher dose
- Fainting, hypotension (abnormally low blood pressure), especially when you stand up or sit down quickly
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath
- Stomach or gut pain, diarrhoea, indigestion, feeling or being sick
- Skin rash with or without raised area
- Chest pain
- Cramps or pain in your muscles
- Blood tests showing more potassium than usual in your blood.

**Uncommon** (affects less than 1 in 100 people)

- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, pricking, burning or creeping on your skin (paraesthesia)
- Loss or change in the way things taste
- Sleep problems
- Feeling depressed, anxious, more nervous than usual or restless
- Blocked nose, difficulty breathing or worsening of asthma
- A swelling in your gut called "intestinal angioedema" presenting with symptoms like abdominal pain, vomiting and diarrhoea
- Heartburn, constipation or dry mouth
- Passing more water (urine) than usual over the day

- Sweating more than usual
- Loss or decrease of appetite (anorexia)
- Increased or irregular heartbeats. Swollen arms and legs. This may be a sign of your body holding onto more water than usual
- Flushing
- Blurred vision
- Pain in your joints
- Fever
- Sexual inability in men, reduced sexual desire in men or women
- An increased number of certain white blood cells (eosinophilia) found during a blood test
- Blood tests showing changes in the way your liver, pancreas or kidneys are working.

**Rare** (affects less than 1 in 1,000 people)

- Feeling shaky or confused
- Red and swollen tongue
- Severe flaking or peeling of the skin, itchy, lumpy rash
- Nail problem (e.g. loosening or separation of a nail from its bed)
- Skin rash or bruising
- Blotches on your skin and cold extremities
- Red, itchy, swollen or watery eyes
- Disturbed hearing and ringing in your ears
- Feeling weak
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets or in the amount of haemoglobin.

**Very rare** (affects less than 1 in 10,000 people)

- Being more sensitive to the sun than usual.

**Other side effects reported:**

Please tell your doctor if any of the following gets serious or lasts longer than a few days.

- Difficulty concentrating
- Swollen mouth
- Blood tests showing too few blood cells in your blood
- Blood tests showing less sodium than usual in your blood
- Fingers and toes changing colour when you are cold and then tingling or feeling painful when you warm up (Raynaud's phenomenon)
- Breast enlargement in men
- Slowed or impaired reactions
- Burning sensation
- Change in the way things smell
- Hair loss.

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

**5. HOW TO STORE NORMOPRIL**

Keep out of the reach and sight of children.

Store below 25°C. Keep in the original packaging to protect from light and humidity.

**Expiry:**

Do not use NORMOPRIL after the expiry date shown on the packaging after "Exp". The expiry date is the last day of the month indicated.

Medicinal products should not be poured down the drain or thrown into the rubbish. Ask your pharmacist how to dispose of packaging and medicinal products you do not need. This will help protect the environment.

**6. FURTHER INFORMATION**

**What NORMOPRIL contains**

**Composition of NORMOPRIL 2.5 mg tablets**

The active substance is ramipril. Each tablet contains 2.5 mg of ramipril.

The other components (excipients) are: microcrystalline cellulose, pregelatinised maize starch, low-substituted hydroxypropylcellulose, yellow iron oxide (E-172), sodium hydrogen carbonate and magnesium stearate.

**Composition of NORMOPRIL 5 mg tablets**

The active substance is ramipril. Each tablet contains 5 mg of ramipril.

The other components (excipients) are: microcrystalline cellulose, pregelatinised maize starch, low-substituted hydroxypropylcellulose, red iron oxide (E-172), sodium hydrogen carbonate and magnesium stearate.

**Composition of NORMOPRIL 10 mg tablets**

The active substance is ramipril. Each tablet contains 10 mg of ramipril.

The other components (excipients) are: microcrystalline cellulose, pregelatinised maize starch, low-substituted hydroxypropylcellulose, red iron oxide (E-172), sodium hydrogen carbonate and magnesium stearate.

**What NORMOPRIL looks like and contents of the package**

NORMOPRIL 2.5 mg tablets are elongated, scored, biconvex, yellow tablets in packages of 28 tablets.

NORMOPRIL 5 mg tablets are elongated, scored, biconvex, pink tablets in packages of 28 tablets.

NORMOPRIL 10 mg tablets are round, scored, biconvex, pink tablets in packages of 28 tablets.

**Marketing Authorisation Holder and Manufacturer**

LABORATORIOS NORMON, S.A.

Ronda de Valdecarrizo, 6 – 28760 Tres Cantos – Madrid (SPAIN)

**This leaflet was last revised in September 2017**

This leaflet does not contain all information about your medicine. If you have any questions or are unsure about anything, ask your doctor or pharmacist.