

AMPRIL HL 2,5 mg/12,5 mg tablets

AMPRIL HD 5 mg/25 mg tablets

RAMIPRIL / HYDROCHLOROTIAZIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 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 •

What is in this leaflet?

1. What Ampril HL and Ampril HD are and what they are used for and what it is used for
2. Before you take Ampril HL and Ampril HD
3. How to take Ampril HL and Ampril HD
4. Possible side effects
5. How to store Ampril HL and Ampril HD
6. Further information

1. WHAT AMPRIL HL AND AMPRIL HD ARE AND WHAT ARE THEY USED FOR

The active substances in Ampril HL and Ampril HD are ramipril and hydrochlorothiazide. Ramipril belongs to a group of medicines that we call "ACE-inhibitors" (angiotensin-converting-enzyme inhibitor).

Ramipril tablets decrease your body's production of substances that could raise your blood pressure, making your blood vessels relaxed and widen, making it easier for your heart to pump blood around your body. Hydrochlorothiazide belongs to a group of medicines called "thiaside diuretics" or water tablets. It works by increasing the amount of urine and thereby reduces blood pressure. Ampril HL and Ampril HD are medicines intended for lowering the blood pressure. The two active substances act together to lower the blood pressure. They are used together when treatment with one active substance does not work.

2. BEFORE YOU TAKE HL AMPRIL AND AMPRIL HD

Do not take Ampril HL and Ampril HD:

- If you are allergic (hypersensitive) to ramipril, hydrochlorothiazide or to any ingredient in Ampril HL or Ampril HD (see Section 6);

- If you are allergic (hypersensitive) to medicines similar to Ampril HL or Ampril HD (other ACE-inhibitors or other medication, sulfonamide); signs of an allergic reaction may include rash, difficulty swallowing or breathing problems, swelling of the lips, face, throat or tongue;
- If you have ever had a severe allergic reaction called "angioedema". The signs include itching, hives (urticaria), red spots on hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing;
- If you have ever had angioneurotic edema in other circumstances;
- If you have ever been on dialysis or any other type of blood filtration. Depending on the type of appliance that was used, Ampril HL or Ampril HD may not be suitable for you.
- If you have severe kidney disease with the reduced supply of blood to the kidneys (renal artery stenosis);
- If you have severe liver damage;
- During the last 6 months of pregnancy (see section "pregnancy and breast-feeding");
- If you are breast-feeding (see section "pregnancy and breast-feeding");
- If you have diabetes or impaired kidney function and you are treated with blood pressure-lowering medicine containing aliskiren.

Do not take Ampril HL or Ampril HD if any of the above mentioned applies to you. If you are not sure, talk to your doctor before taking Ampril HL or Ampril HD.

Take special care with Ampril HL and Ampril HD:

Consult your doctor or pharmacist before taking the medicine:

- If you have problems with heart, liver or kidneys;
- If you have lost a lot of salt or fluid (due to sickness (vomiting), if you have had diarrhea, if you sweat more than usual,
- if you are on a low salt diet, if you are taking diuretics (water tablets) for a long time or you are on dialysis
- if you are going to have a 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 discontinue the treatment with Ampril HL or Ampril HD one day before surgery. Ask your doctor for advice;
- If you have a high level of potassium in the blood (shown in the blood tests results);
- If you have collagen vascular disease such as scleroderma or systemic lupus erythematosus;

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, telmesartan, irbesartan), in particular if you have diabetes-related kidney problems.
- Aliskerin

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium or sodium) in your blood at regular intervals. See also information under the heading 'Do not take Ampril HL or Ampril HD tablets'.

You must tell the doctor if you think you are (or might become) pregnant. Ampril HL and Ampril HD are not recommended during the first 3 months of pregnancy, and after 3 months they can seriously harm your child (see section below: "pregnancy and breast-feeding").

Children

Ampril HL or Ampril HD tablets are not recommended for use in children and adolescents under 18 years of age because safety and efficacy of Ampril HL or Ampril HD tablets in children has not yet been established.

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

Other medicines and Ampril HL or Ampril HD tablets

Tell your doctor, pharmacist or nurse if you are taking or have recently taken or might take any other medicines. This is because Ampril HL or Ampril HD tablets can affect the way some other medicines work. Also some medicines can affect the way Ampril HL or Ampril HD tablets work.

Please tell your doctor if you are taking any of the following medicines. They can reduce the effect of Ampril HL or Ampril HD tablets: medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and aspirin), medicines used for the treatment of low blood pressure, shock, cardiac 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 experiencing side effects if you take them with Ampril HL or Ampril HD tablets:

- medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin 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)
- cholestyramine (for lowering the amount of fat in the blood)
- carbamazepine (for epilepsy)

Please tell your doctor if you are taking any of the following medicines.

They may be affected by Ampril HL and Ampril HD tablets:

- medicines for diabetes such as oral glucose-lowering medicines and insulin. Ampril HL and Ampril HD tablets may lower your blood sugar levels. Check your blood sugar levels more often while taking Ampril HL and Ampril HD tablets
- lithium (for mental health problems). Ampril HL and Ampril HD tablets may increase the amount of lithium in your blood. Your lithium amount will need to be closely checked by your doctor.
- Medicines for muscle relaxation.
- quinine (for malaria).
- medicines that contain iodine (they can be used if you are subjected to the scans or x-rays in hospital).
- penicillin (for infection)
- medicine for thinning the blood you are taking by mouth (oral anticoagulants), such as warfarin.

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 Ampril HL and Ampril HD tablets' and 'Warnings and precautions') If any of the above apply to you (or you are not sure), talk to your doctor before taking Ampril HL and Ampril HD tablets.

Tests

Check with your doctor or pharmacist before taking the medicine: If you are testing the parathyroid function. Ampril HL and Ampril HD can affect the results of the tests. If you are an athlete and you are tested on doping, Ampril HL and Ampril HD can cause a positive result.

Taking food and drinks with Ampril HL and Ampril HD

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

Pregnancy and breast-feeding

You must tell your doctor if you think that you are (or might become) pregnant. You should not take Ampril HL and Ampril HD tablets during the first 12 weeks of pregnancy, and you must not take them at all after the 13th week as their use during pregnancy may possibly be harmful to the baby. If you become pregnant while taking Ampril HL and Ampril HD tablets, tell your doctor immediately. If you are planning a pregnancy, it is necessary to switch to the appropriate alternative treatment. You should not take Ampril HL and Ampril HD tablets if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Driving and using machines

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

Other precautions

This medicine contains lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE AMPRIL HL AND AMPRIL HD TABLETS

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is 1 Ampril HL tablet (2.5 mg of ramipril and 12.5 mg of hydrochlorothiazide) in the morning. If necessary, the dose can be increased to 1 Ampril HD tablet (5 mg of ramipril and 25 mg of hydrochlorothiazide) in the morning, but only after three weeks. The maximum dose is 5 mg of ramipril and 25 mg of hydrochlorothiazide.

Taking Ampril HL or Ampril HD

Take this medicine by mouth every day at the same time, usually in the morning. Swallow the tablet with a liquid. Do not crush or chew the tablet.

How to take Ampril HL or Ampril HD

The treatment of high blood pressure

Your doctor will determine how much medicine you need to take to keep your blood pressure under control.

Older people

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

If you take more Ampril HL and Ampril HD than you should

If you think you have taken more tablets than specified in this leaflet, or that is prescribed by a doctor, immediately contact your doctor, ambulance services or pharmacist. 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 forget to take HL Ampril and Ampril HD

If you forget to take a dose, take your next dose at the usual time. Do not take a double dose to make up for a missed dose. If you have any further questions about the application of Ampril HL and Ampril HD talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

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

Very common: Appear in more than 1 in 10 patients

Common: Appear at 1 to 10 patients on 100 patients

Uncommon: Appear at 1 to 10 patients on 1000 patients

Rare: Appear at 1 to 10 patients on 10000 patients

Very rare: Appear at fewer than 1 patient in the 10000 patients

Unknown frequency: Not possible to evaluate from available data

Stop taking Ampril HL and Ampril HD tablets and contact your doctor immediately, if you notice any of the following serious side effects - you may need urgent medical treatment:

- Swelling of the face, lips or throat which makes it difficult to swallow or breathe, as well as itching and rashes. This could be a sign of a severe allergic reaction to Ampril HL and Ampril HD tablets.
- 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 multiforme).

Contact your doctor immediately, if you notice any of the following:

- 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 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.

Tell your doctor if you notice any of the following side effects or they get worse:

Common (may affect up to 1 in 10 people)

- Headache or feeling tired
- Feeling dizzy. This is more likely to happen when you start taking Ramipril tablets or start taking a higher dose
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- Dry tickly cough, inflammation of your sinuses (sinusitis) or bronchitis, shortness of breath • Stomach or gut pain, diarrhea, 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 (may affect up to 1 in 100 people)

- Balance problems (vertigo)
- Itching and unusual skin sensations such as numbness, tingling, prickling, 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 diarrhea
- 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 (may affect up to 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 hemoglobin.

Very rare (may affect up to 1 in 10,000 people)

- nausea, diarrhea or heartburn
- Red, swollen tongue or dry mouth
- blood tests are showing more potassium in your blood than usual

Other reported side effects

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

- Difficulties with the recollection, restlessness or distractions
- fingers on the hands and feet change color when you're out in the cold and or hurt when they warm up. It could be Raynaud's syndrome.
- Increased breast in men
- Blood clots
- Hearing disorders
- Less tearing than usual
- Viewing objects in yellow

- Dehydration
- Swelling, pain and redness of the face (inflammation of a salivary gland cancer)
- Swelling of the intestines, which is called "intestinal angioedema", and involves stomach pain, vomiting and diarrhea
- Greater sensitivity to sunlight than usual
- peeling of the skin,
- painful rash that itches or other skin reactions, eg. red rash on face or forehead skin
- rashes or bruises bright spots on the skin and cold extremities
- difficulties with your fingernails (e.g. loosening or separation of the nail from the base of the)
- Musculoskeletal stiffness or inability to move the jaw (tetany)
- weakness or cramps
- reduced sexual desire in men or women
- blood in the urine (urine), which can be a sign of trouble with kidney problems (interstitial nephritis)
- more sugar in the urine (urine) than usual
- an increased number of certain white blood cells (Eosinophilia) in blood tests
- blood tests showing too few blood cells (pancytopenia) in your blood
- blood tests that show the changed amount of salts such as sodium, calcium, and magnesium chlorides in your blood
- slow or decreased responsiveness changed the scent of things
- heavy breathing or worsening of asthma

5. HOW TO STORE AMPRIL HL AND AMPRIL HD

Keep out of the reach and sight of children.

Keep at temperature below 30 ° c.

Do not use Ampril HL and Ampril HD after the expiry date indicated on the packaging.

The shelf life of the medicinal product is 24 months from the date of manufacture.

Expiration date

Expiration date refers to the last day of that month. The medicine must not be thrown in the waste water or among the household waste. If you are about to remove a medicine that you no longer need, consult a pharmacist. Such actions help to save the environment.

6. ADDITIONAL INFORMATION

What Ampril HL and Ampril HD contain?

Active substances in tablets Ampril Ampril HL and HD are ramipril and hydrochlorothiazide. One Ampril HL Tablet contains 2.5 mg of ramipril and 12.5 mg hydrochlorothiazide. One Ampril HD Tablet contains 5 mg of ramipril and 25 mg of hydrochlorothiazide. The other ingredients are sodium-hydrogen carbonate, lactose monohydrate, cross-linked sodium-carmelosate, pregelatinised starch, and sodium stearyl fumarate.

The content and method of packing Ampril HL and Ampril HD

Ampril HL: white to almost white, oval, uncoated, flat tablets with divider line on one side and the label 12.5.

Ampril HD: a white to almost white, oval, uncoated, flat tablets with the label 25. There are boxes with 28 tablets. (4 blisters by 7 tablets)

Regime of dispensing

The medicine is issued on prescription.

Manufacturer

KRKA d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer of the medicinal product

KRKA d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia