

Ramikor H 2,5 mg/12,5 mg tablets

Ramikor H 5 mg/12,5 mg tablets

Ramipril / Hydrochlorothiazide

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. See section 4.

What is in this leaflet

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

1. What Ramikor H is and what it is used for

Ramikor H contains the active substances ramipril and hydrochlorothiazide. Ramipril belongs to a group of medicines called ACE inhibitors (Angiotensin Converting Enzyme Inhibitors) while hydrochlorothiazide belongs to a group of medicine called thiazide diuretics.

Diuretics are also known as water tablets. These cause you to produce more urine. This helps to lower your blood pressure.

The two active substances in Ramikor H work together to lower your blood pressure.

They work better together than either would work alone.

Ramikor H works by:

- decreasing the production of substances in your body that could raise the blood pressure;
- making the blood vessels relax and widen;
- making it easier for the heart to pump blood in the body.

Ramikor H is used:

- to treat high blood pressure (hypertension);
- to prevent cardiovascular diseases (history of ischemic heart disease or stroke, or peripheral vascular diseases; diabetes with at least one risk factor for cardiovascular disease);
- to reduce the risk or delay the worsening of kidney problems (whether or not you have diabetes);
- to treat the heart when it cannot pump enough blood to the rest of the body (heart failure);
- as treatment following heart attack (myocardial infarction) complicated with heart failure.

You should use Ramikor H when previous treatment with Ramipril alone has not worked well enough.

2. What you need to know before you take Ramikor H:

Do not take Ramikor H:

- if you are allergic to ramipril, any other ACE inhibitor, hydrochlorothiazide, medicines containing sulphamide or any of the other ingredients of this medicine (listed in section 6). Signs of an allergic reaction may include a rash, swallowing or breathing problems, swelling of the lips, face, throat or tongue.
- you have ever had a serious allergic reaction called "angioedema". The signs include itching, hives (urticaria), reddening of the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing;
- you are having dialysis or any other type of blood filtration. Depending on the apparatus that is used, Ramikor H may not be suitable for you;
- you have kidney problems where the blood supply to your kidneys is reduced (renal artery stenosis);
- you are in the last 6 months of pregnancy (see section on Pregnancy and breast-feeding below);
- your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment;
- you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Ramikor H if you:

- have heart, liver or kidney problems;
- have lost a lot of body fluids or salts (through vomiting, diarrhea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) for a long time or having had dialysis);
- Have hypotension (low blood pressure).
- are going to have treatment to reduce an allergy to bee or wasp stings (desensitisation);
- are going to receive an anaesthetic. This may be given for an operation or any dental procedure. You may need to stop your Ramikor H treatment one day beforehand; ask your doctor for advice;
- have high amounts of potassium in your blood (shown in blood test results);
- have collagen vascular disease such as scleroderma or systemic lupus erythematosus;
- tell your doctor if you think you are pregnant (or might become pregnant). Ramikor H is not recommended for use during the first 3 months of pregnancy, and may harm seriously your baby after the third month of pregnancy (see section on "Pregnancy and breastfeeding" below).

If you are taking any of the following medicines used to treat high blood pressure:

- An angiotensin II receptor blocker (ARB) (also known as sartans – for example valsartan, telmisartan, 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) in your blood at regular intervals.

See also information under the heading "Do not take Ramikor H".

Children:

Ramikor H is not recommended for use in children below 18 years of age because safety and efficacy of Ramikor H 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 Ramikor H.

Other medicines and Ramikor H

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including nonprescription medicines (including herbal medicines). Ramikor H can affect the way some other medicines work. Also some medicines can affect the way Ramikor H work.

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

- medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and acetyl salicylic acid);
- 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 getting side effects if you take them together with Ramikor H:

- medicines used to relieve pain and inflammation (e.g. Non-Steroidal Anti-inflammatory Drugs (NSAIDs) such as ibuprofen or indomethacin and acetyl salicylic acid);
- medicines for cancer (chemotherapy);
- medicines to stop the rejection of organs after a transplant, such as cyclosporin;
- diuretics (water tablets) such as furosemide;
- medicines which can increase the amount of potassium in the 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 level of uric acid in the blood);
- procainamide (for heart rhythm problems).

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

- medicines for diabetes such as oral glucose lowering medicines and insulin. Ramikor H may lower the amount of blood sugar. Check your blood sugar amounts closely while taking Ramikor H;
- lithium (for mental health problems), Ramikor H may increase the amount of lithium in the blood. Your lithium amount will need to be closely checked by your doctor;
- trimethoprim and co-trimoxazole (for infections caused by bacteria);
- temsirolimus (for cancer);
- everolimus (for prevention of transplant rejection);
- tacrolimus (used to control immune response enabling the body to accept the transplanted organ).
- Sympathomimetics which may be found in some decongestants, cough/cold medicines.
- Skeletal muscle relaxants used to relieve muscle spasms, including tubocurare.
- Neutral endopeptidase (NEP) inhibitors.
- Digitalis preparations, active substances known to prolong the QT interval and antiarrhythmics: their proarrhythmic toxicity may be increased or their antiarrhythmic effect decreased in the presence of electrolyte disturbances (e.g. hypokalaemia, hypomagnesaemia).
- Methylcopa: Haemolysis possibility.
- Colestyramine or other enterally administered ion exchangers: reduced absorption of hydrochlorothiazide. Sulphonamide diuretics should be taken at least one hour before or four to six hours after these medications.
- Calcium salts and plasma calcium increasing medicinal products: Rise in serum calcium concentration is to be anticipated in case of concomitant administration of hydrochlorothiazide; therefore close monitoring of serum calcium is required.
- Carbamazepine: risk of hyponatraemia due to additive effect with hydrochlorothiazide.
- Iodine containing contrast media: in case of dehydration induced by diuretics including hydrochlorothiazide, there is increased risk of acute renal impairment, in particular when use of important doses of iodine containing contrast media.
- Penicillin: hydrochlorothiazide is excreted in the distal tubulus, and reduces excretion of penicillin.
- Quinine : hydrochlorothiazide reduces quinine excretion.

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 heading "Do not take Ramikor H" and "Warnings and precautions").

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

Ramikor H with food, drink and alcohol

- Drinking alcohol with Ramikor H may make you feel dizzy or light-headed. If you are taking Ramikor H, discuss with your doctor how much alcohol you can drink , as medicines used to reduce blood pressure and alcohol can have additive effects;
- Ramikor H 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 that you are (or might become) pregnant. You should not take Ramikor H in the first 12 weeks of pregnancy, and you must not take it at all after the 13th week as its use during pregnancy may possibly be harmful to the baby.

If you become pregnant while taking Ramikor H, tell your doctor immediately. A

switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy.

Breast-feeding

You should not take Ramicor H if you are breast-feeding.

Driving and using machines

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

3. How to take Ramicor H

Always take this medicine exactly as your doctor or pharmacist has told you. Ask your doctor or pharmacist if you are not sure.

Method of administration

Take this medicine by mouth at the same time of the day each day. Generally, it is recommended that the daily dose be administered in the morning. Swallow the tablets with liquid. Do not crush or chew the tablets.

Dosage:

- Treatment of high blood pressure

The dose should be individualised according to the patient profile and blood pressure control. The administration of the fixed combination of ramipril and hydrochlorothiazide is usually recommended after dosage titration with one of the individual components.

Ramicor H should be started at the lowest available dosage. If necessary, the dose can be progressively increased to achieve target blood pressure; the maximum permitted doses are 10 mg of ramipril and 25 mg of hydrochlorothiazide daily.

Special populations

- Elderly

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

If you take more Ramicor H than you should

Tell a doctor or go to the nearest hospital straight away. Do not drive to the hospital, get somebody else to take you or call for an ambulance. Take the medicine pack with you so that the doctor knows what you have taken.

If you forget to take Ramicor H

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 tablet.

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

4. Possible side effects

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

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

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 a cough. These could be signs of lung problems.
- Bruising more easily, bleeding for longer periods of time, any bleeding (e.g. bleeding from the gums), and purple spots on the skin, getting infections more easily, sore throat and fever, feeling tired, dizzy or having pale skin. These can be signs of blood or bone marrow problems.
- Severe stomach pain which may reach through to the back. This could be a sign of pancreatitis (inflammation of the pancreas).
- Fever, chills, tiredness, loss of appetite, stomach pain, feeling sick, yellowing of the skin or eyes (jaundice). These can be signs of liver problems such as hepatitis (inflammation of the liver) or liver damage.
- Hydrochlorothiazide in Ramicor H can cause Sudden Eye Disorders:
 - Myopia: sudden nearsightedness or blurred vision.
 - Glaucoma: an increased pressure in your eyes, eye pain.
- Untreated, it may lead to permanent vision loss.

These eye disorders are related and can develop within hours to weeks of starting Ramicor H.

You may become sensitive to the sun while taking Ramicor H. Exposure to sunlight should be minimized until you know how you respond.

Other side effects:

Tell your doctor if you notice any of the following side effects get worse or last longer than a few days:

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 Ramicor H or start taking a higher dose
- Fainting, hypotension (abnormally low blood pressure), especially when you stand or sit up quickly
- Dry irritating cough, inflammation of the sinuses (sinusitis) or bronchitis, shortness of breath
- Stomach or gut pain, diarrhoea, indigestion, feeling or being sick
- Skin rash with or without swelling
- Chest pain
- Cramps or pain in the muscles
- Blood tests showing increased levels of potassium in the 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 taste
- Sleep problems
- Feeling depressed, anxious, more nervous or restless than usual
- Blocked nose, difficulty breathing or worsening of asthma
- A swelling in the gut called "intestinal angioedema" presenting with symptoms like abdominal pain, vomiting and diarrhoea

- Heartburn, constipation or dry mouth
- Passing more 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 fluid retention in the body.
- Flushing
- Blurred vision
- Pain in the joints
- Fever
- Male sexual dysfunction, 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 function of the liver, pancreas or kidneys.

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

- Feeling insecure or confused
- Red and swollen tongue
- Severe flaking or peeling of the skin, itchy, raised rash
- Nail problems (e.g. loss or separation of a nail from its bed)
- Skin rash or bruising
- Blotches on the skin and cold extremities
- Red, itchy, swollen or watery eyes
- Impaired hearing and ringing in the ears
- Feeling weak
- Blood tests showing a decrease in the number of red blood cells, white blood cells or platelets, or low haemoglobin level.

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

- Being more sensitive to the sun than usual.

Unknown frequency (frequency cannot be estimated from the available data)

- Concentrated urine (dark coloured), nausea or vomiting, muscle cramps, confusion and fainting that may be due to inadequate secretion of ADH (antidiuretic hormone). If you experience these symptoms, contact your doctor soonest possible.

Athletes

- Hydrochlorothiazide may produce a positive analytic result in the anti-doping test.

Metabolic and endocrine effects

Thiazide therapy may impair glucose tolerance. In diabetic patients dosage adjustments of insulin or oral hypoglycaemic agents may be required. Latent diabetes mellitus may become manifest during thiazide therapy. Increases in cholesterol and triglyceride levels have been associated with thiazide diuretic therapy. Hyperuricaemia may occur or frank gout may be precipitated in certain patients receiving thiazide therapy.

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 lips
- Blood tests showing too few blood cells in the blood
- Blood tests showing less sodium than usual in the 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 smell perception
- Hair loss

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system.

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

5. How to store Ramicor H

Store below 30°C.

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. The expiry date refers to the last day of that month.

Do not throw away any medicines via waste water or house hold 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 Ramicor H contains

Ramicor H 2,5 mg/12,5 mg

- The active substances are ramipril 2,5 mg and hydrochlorothiazide 12,5 mg.
- The other ingredients are: microcrystalline cellulose, maize starch pregelatinized, hypromellose, stearic acid, red iron oxides.

Ramicor H 5 mg/12,5 mg

- The active substances are ramipril 5 mg and hydrochlorothiazide 12,5 mg.
- The other ingredients are: microcrystalline cellulose, maize starch pregelatinized, hypromellose, stearic acid, yellow iron oxides.

What Ramicor H looks like and contents of the pack

Ramicor H 2,5 mg/12,5 mg

Red round tablets.
15 tablets in Al/PVC foil blister packs.
2 (two) blisters with a leaflet in a carton box.

Ramicor H 5 mg/12,5 mg

Yellow round tablets.
15 tablets in Al/PVC foil blister packs.
2 (two) blisters with a leaflet in a carton box.

Marketing Authorisation Holder and Manufacturer

Adipharm EAD
130 Simeonovsko shosse Blvd
1700 Sofia, Bulgaria

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