

Package leaflet: Information for the user

Ramipril Aurobindo 5 mg tablets **Ramipril Aurobindo 10 mg tablets** Ramipril

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

1. What Ramipril Aurobindo is and what it is used for

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

Ramipril Aurobindo 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.

Ramipril Aurobindo 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. What you need to know before you take Ramipril Aurobindo

Do not take Ramipril Aurobindo

- If you are allergic to ramipril, any other ACE inhibitor medicine or any of the ingredients of this medicine (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, Ramipril Aurobindo may not be suitable for you

- If you have kidney problems where the blood supply to your kidney is reduced (renal artery stenosis)
- During the last 6 months of pregnancy (see section below on “Pregnancy and breast-feeding”)
- 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 Ramipril Aurobindo if any of the above apply to you. If you are not sure, talk to your doctor before taking Ramipril Aurobindo.

Warnings and precautions

Talk to your doctor or pharmacist before taking your Ramipril Aurobindo:

- If you have heart, liver or kidney problems
- If you have lost a lot of body salts or fluids (through being sick (vomiting), having diarrhea, sweating more than usual, being on a low salt diet, taking diuretics (water tablets) 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 Ramipril Aurobindo 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. Ramipril Aurobindo 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 below “Pregnancy and breast-feeding”).
- 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 Ramipril Aurobindo”

Children

Ramipril Aurobindo is not recommended for use in children and adolescents below 18 years of age because safety and efficacy of Ramipril 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 Ramipril Aurobindo.

Other medicines and Ramipril Aurobindo

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Ramipril Aurobindo can affect the way some other medicines work. Also some medicines can affect the way Ramipril Aurobindo works.

Please tell your doctor if you are taking any of the following medicines. They can make the effect of Ramipril Aurobindo weaker:

- 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, 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 with Ramipril Aurobindo:

- 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).
- Trimethoprim and co-trimoxazole (for infections caused by bacteria)
- Temsirolimus (for cancer)
- Everolimus (for prevention of graft rejection)

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

- Medicines for diabetes such as oral glucose lowering medicines and insulin. Ramipril Aurobindo may lower your blood sugar amounts. Check your blood sugar amounts closely while taking Ramipril Aurobindo
- Lithium (for mental health problems). Ramipril Aurobindo 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 Ramipril Aurobindo.

Please tell your doctor if you are taking any of the following medicines. 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 Ramipril Aurobindo” and “Warnings and precautions”)

Ramipril Aurobindo with food, drink and alcohol

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

Pregnancy, breast-feeding and fertility

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. You should not take Ramipril in 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 on Ramipril, tell your doctor immediately. A switch to a suitable alternative treatment should be carried out in advance of a planned pregnancy. You should not take Ramipril if you are breast-feeding.

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.

Driving and using machines

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

Ramipril Aurobindo contains lactose monohydrate. 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 Ramipril Aurobindo

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

Ramipril Aurobindo 5 mg tablets:

This strength is not suitable for dosages below 2.5mg

Ramipril Aurobindo 10 mg tablets:

This strength is not suitable for dosages below 5 mg

For doses less than 2.5 mg per day Ramipril Aurobindo is not suitable. Other medicinal products of ramipril in adequate strength are available. Your doctor will advise you accordingly.

Taking this medicine

- Take this medicine by mouth at the same time of the day each day.
- Ramipril Aurobindo may be taken with or without food.
- 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 (water tablets), your doctor may stop or reduce the amount of the diuretic you take before beginning treatment with Ramipril Aurobindo.

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 be started on 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 Ramipril Aurobindo than you should

Tell a doctor or go to the nearest hospital casualty department 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. This is so the doctor knows what you have taken.

If you forget to take Ramipril Aurobindo

- 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 Ramipril Aurobindo 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 Ramipril Aurobindo
- 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 Ramipril Aurobindo 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 (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 heartbeat, 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 problems (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

Not known (Frequency cannot be estimated from the available data)

concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible.

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

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 Ramipril Aurobindo

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

Store below 25°C.

Store in the original package in order to protect from moisture.

Keep the HDPE container tightly closed in order to protect from moisture.

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

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 Ramipril Aurobindo contains

- The active substance is ramipril. Each tablet contains 5 mg or 10 mg of ramipril.
- The other ingredients are starch pregelatinised (maize), lactose monohydrate, sodium hydrogen carbonate (E500), croscarmellose sodium (E468), iron oxide red [for 5mg tablets only] (E172) and sodium stearyl fumarate.

What Ramipril Aurobindo looks like and contents of the pack

Ramipril Aurobindo 5 mg tablets:

Light pink coloured mottled, flat faced bevel edged round [diameter 6.0 mm] uncoated tablet debossed with “H” and “19” separated by scoreline on one side and plain on other side. The tablet can be divided into two equal doses.

Ramipril Aurobindo 10 mg tablets:

White to Off-white colored, flat faced bevel edged round [diameter 8.0 mm] uncoated tablet debossed with “H” and “20” separated by scoreline on one side and plain on other side. The tablet can be divided into two equal doses.

Ramipril Aurobindo tablets are available in:

Blister pack (Clear PVC/ Aluminium).

- White opaque HDPE container with PP screw cap

Pack sizes:

Ramipril Aurobindo 5 mg tablets:

Blister pack: 7, 10, 14, 20, 28, 30, 42, 50, 56, 60, 90, 98, 100 and 500 tablets

HDPE container pack: 30 and 1000 (clinical pack) tablets

Ramipril Aurobindo 10 mg tablets:

Blister pack: 20, 28, 30, 50, 56, 60, 90, 98, 100 and 500 tablets

HDPE container pack: 30 and 1000 (clinical pack) tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aurobindo Pharma (Malta) Limited
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Malta

Manufacturer

Milpharm Limited
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United Kingdom

or

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate
Hal Far, Birzebbugia, BBG 3000
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or

Galenicum Health, S.L
Avda. Cornellá 144, 7^o-1^a Edificio LEKLA,
Esplugues de Llobregat 08950, Barcelona,
Spain

This medicinal product is authorised in the Member States of the EEA under the following names:

Denmark	Ramipril Aurobindo
Estonia	Ramipril Aurobindo
Finland	Ramipril Orion 5 mg / 10 mg tabletti
France	RAMIPRIL ARROW LAB 5 mg / 10 mg, comprimé sécable
Germany	Ramipril Aurobindo 5 mg / 10 mg Tabletten
Greece	RAMISYN 5 mg / 10 mg δισκία
Ireland	Ramipril Aurobindo 5 mg / 10 mg tablets
Italy	Ramipril Aurobindo 5 mg / 10 mg compresse
Lithuania	Ramipril Aurobindo 5 mg / 10 mg tabletės
Malta	Ramipril Aurobindo 5 mg / 10 mg tablets
Netherlands	Ramipril Aurobindo 5 mg / 10 mg, tabletten
Norway	Ramipril Aurobindo 5 mg / 10 mg tabletter
Poland	Ramipril Aurobindo
Romania	Ramipril Aurobindo 5 mg / 10 mg comprimate
Spain	ramipril cinfa 5 mg / 10 mg comprimidos EFG
Sweden	Ramipril Aurobindo 5 mg / 10 mg tabletter
United Kingdom	Ramipril 5 mg / 10 mg tablets

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