RAMIL TABLET

Ramipril (5mg, 10mg)

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1. What Ramil is used for

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

Ramil can be used:

- To treat high blood pressure
- To reduce the risk of you having a heart attack or stroke
- To treat your heart when it cannot pump enough blood to the rest of your body (heart failure)
- As treatment to following heart attack complicated with heart failure

2. How Ramil works

Ramil 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

3. Before you use Ramil

- When you must not use Ramil

Do not take Ramil if:

- You are allergic to ramilpril, any other ACE inhibitor medicine or any of the ingredients of Ramil.
- You ever had a serious allergic reaction called "angioedema".
- You are having dialysis or any other type of blood filtration. Depending on the type of machine that is used, Ramil may not be suitable for you

- You have kidney problems where the blood supply to you kidney is reduced
- You are pregnant, especially during the last 6 months of pregnancy.
- Your blood pressure is abnormally low or unstable. Your doctor will need to make this assessment.

- Before you start to use Ramil

Check with your doctor or pharmacist before taking Ramil if:

- If you have heart, liver or kidney problems
- If you have lost a lot of body salts or fluids
- If you are going to have treatment to reduce your allergy to bee or wasp stings
- If you are going to receive an aneasthetic
- If you have high amount of potassium in your blood
- If you have collagen vascular disease such as scleroderma or systemic lupus erythematosus
- You must tell your doctor if you think that you are pregnant

- Taking 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 (including herbal medicines). Ramil can affect the way some other medicines work.

Medicines that make Ramil work less well:

- Medicines used to relieve pain and inflammation such as ibuprofen and aspirin
- Medicines used for the treatment of low blood pressure, shock, cardiac failure, asthma or allergies such as ephedrine, noradrenaline or adrenaline.

Medicines that can increase the change or getting side effects if you take them with Ramil:

Medicines used to relieve pain and inflammation

- Medicines for cancer
- Medicines to stop rejection of organs after a transplant such as ciclosporin
- Diuretics such as furosemide
- Medicines which can increase the amount of potassium in your body
- Steroid medicines for inflammation such as prednisolone
- Allopurinol (used to lower the uric acid in your blood)
- Procainamide (for heart rhythm problems).

4. How to use Ramil

- How much to use

Always take Ramil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. The tablets can be divided into equal halves. Do not chew or crush the tablets.

- When to use Ramil

Take Ramil by mouth at the same time of the day each day. Swallow the tablet whole with at least ½ glass of water.

- How long to use Ramil

Take Ramil as long as your doctor advise you to take.

- If you forget to use Ramil

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 use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

The symptom of overdosage would be low blood pressure, shock, slow heart rate, electrolyte disturbances and kidney failure.

5. While you are using it

- Things you must do

You must tell your doctor if you think that you are (or might become) pregnant.

You should not take Ramil during pregnancy or if you are breast-feeding.

- Things you must not do

Do not drive or use any tools or machines when you start taking Ramil or start taking a higher dose. You may feel dizzy.

- Things to be careful of

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

6. Side effects

Stop taking Ramil and see a doctor straight away if you notice any of the following serious 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.
- 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, chest pain, tightness in your chest or more serious problems including heart attack and stroke
- Shortness of breath or a cough
- Bruising more easily, bleeding for longer than normal, any sign of bleeding (eg. Bleeding from the gums), purple spot blotching on the skin or getting infections more easily than usual, sore throat and fever, feeling tired, faint, dizzy or having pale skin.
- Severe stomach pain which may reach through to your back

• Fever, chills, tiredness, loss of appetite, stomach pain, feeling pain, feeling sick, yellowing of your skin or eyes (jaundice)

Other side effects include:

Headache or feeling tired, feeling dizzy, fainting, hypotension, dry tickly cough, inflammation of your sinuses 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.

If you experience other side effect not listed in this leaflet, please tell you doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

7. Storage and Disposal of Ramil

- Storage

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 and blister after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C, in the original package.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description

- What it looks like

Ramil 5mg: Pink, capsule-shape, uncoated, flat tablets, 8.8 x 4.4 mm, scored on one side and side walls, marked R3

Ramil 10mg: White to off white, capsule-shape, un-coated, flat tablet, 11.0 x 5.5 mm, scored on one side and side walls, marked R4

- Ingredients

- Active ingredient
 - Ramil 5mg Tablet contains 5mg ramilpril
 - Ramil 10mg Tablet contains 10mg ramilpril
- Inactive ingredients
 Croscarmellose sodium, ethanol,
 pregelatinized starch, sodium stearyl
 fumarate, lactose monohydrate,
 sodium hydrogen carbonate, iron
 oxide yellow (Ramil 5mg) and iron
 oxide red (Ramil 5mg).

- MAL number

Ramil 5mg : MAL12060001A Ramil 10mg : MAL12060002A

9. Manufacturer

Actavis hf., Reykjavikurvegur 78, IS-220 Hafnarfjörður, Iceland

Product Registration Holder

MILRIN PHARMACEUTICAL CO. (M) SDN. BHD.

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