

LISINOPRIL TABLET[®]

Consumer Medication Information Leaflet (RiMUP)

Lisinopril (5mg, 10mg)

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What *Lisinopril* is used for

Lisinopril is one of a class of medicines known as angiotensin converting enzyme (ACE) inhibitors.

Lisinopril is usually prescribed to:

- Reduce high blood pressure.
- Treat patients with heart failure.

How *lisinopril* works

Lisinopril belongs to a class of medicines known as angiotensin converting enzyme (ACE) inhibitors. ACE inhibitors work mainly by blocking an enzyme in the body that is necessary to produce angiotensin II, a substance that causes blood vessels to constrict (tighten). As a result, ACE inhibitors indirectly relax blood vessels which lowers blood pressure. After taking a dose of *Lisinopril*, the blood pressure lowering effect will be seen after 1 hour, with peak reduction of blood pressure usually achieved by 6 hours after dosing. In some patients, achievement of optimal blood pressure reduction may require 2 to 4 weeks of therapy.

Before you use *Lisinopril*

When you must not use it

- You are allergic (hypersensitive) to *lisinopril* or any of the other ingredients of this product.
- You have ever had an allergic reaction to another ACE inhibitor medicine. The allergic reaction may have caused swelling of the hands, feet, ankles, face, lips, tongue or throat. It may also have made it difficult to swallow or breathe (angioedema).

- A member of your family has had severe allergic reactions (angioedema) to an ACE inhibitor or you have had severe allergic reactions (angioedema) without a known cause.
- If you are more than 3 months pregnant. (It is also better to avoid *lisinopril* in early pregnancy).
- Do not take *lisinopril* if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking *lisinopril*.
- If you develop a dry cough, which is persistent for a long time after starting treatment with *lisinopril*, talk to your doctor.

Pregnancy and lactation

Pregnancy:

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking *Lisinopril* before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of *Lisinopril*. *Lisinopril* 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 breastfeeding or about to start breastfeeding. *Lisinopril* is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely.

Before you start to use it

To make sure you can safely take *lisinopril*, tell your doctor if you have any of these other conditions:

- kidney disease (or if you are on dialysis)
- liver disease
- heart disease or congestive heart failure
- Diabetes or a connective tissue disease such as Marfan syndrome, Sjogren's syndrome, lupus, scleroderma, or rheumatoid arthritis.

- FDA pregnancy category D. Do not use *lisinopril* if you are pregnant. Stop using this medication and tell your doctor right away if you become pregnant. *Lisinopril* can cause injury or death to the unborn baby if you take the medicine during your second or third trimester. Use effective birth control while taking *lisinopril*. It is not known whether *lisinopril* passes into breast milk or if it could harm a nursing baby. Do not use *lisinopril* without telling your doctor if you are breast-feeding a baby.
- You have a narrowing (stenosis) of the aorta (an artery in your heart) or a narrowing of the heart valves (mitral valves).
- You have a narrowing (stenosis) of the kidney artery.
- You have an increase in the thickness of the heart muscle (known as hypertrophic cardiomyopathy).
- You have problems with your blood vessels (collagen vascular disease).
- You have low blood pressure.
- You may notice this as feeling dizzy or light-headed, especially when standing up.
- You have recently had diarrhea or vomiting (being sick).
- Your doctor has told you to control the amount of salt in your diet.
- You have high levels of cholesterol and you are having a treatment called 'LDL apheresis'.
- You are of black origin as *Lisinopril* may be less effective. You may also more readily get the side effect 'angioedema' (a severe allergic reaction).
- If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking *Lisinopril*.

Taking other medicines

Tell your doctor if you are taking, or have recently taken, any other medicines. This includes medicines that you buy without a prescription. This is because *Lisinopril* can affect the way some medicines work and some medicines can have an effect on *Lisinopril*. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Other medicines to help lower your blood pressure.
- Water tablets (diuretic medicines).
- Medicines to break up blood clots (usually given in hospital).
- Beta-blocker medicines, such as atenolol and propranolol.
- Nitrate medicines (for heart problems).
- Non-steroidal anti-inflammatory drugs (NSAIDs) used to treat pain and arthritis.
- Aspirin (Acetylsalicylic acid), if you are taking more than 3 grams each day.
- Medicines for depression and for mental problems, including lithium.
- Potassium tablets or salt substitutes that have potassium in them.
- Insulin or medicines that you take by mouth for diabetes.
- Medicines used to treat asthma.
- Medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy).
- Medicines to suppress the body's immune response (immunosuppressants).
- Allopurinol (for gout).
- Procainamide (for heart beat problems).
- Medicines that contain gold, such as sodium aurothiomalate, which may be given to you as an injection.

How to use Lisinopril

How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Lisinopril should be taken at the same time every day.

Dosage must be individualized and should be adjusted according to blood pressure response.

When to use it

Use as directed by your doctor or pharmacist.

Take *Lisinopril tablets* every day at around the same time. Choose a time that is easy to remember.

Since absorption of *Lisinopril tablets* is not affected by food, the tablets may be administered before, during or after meals. *Lisinopril* should be administered in a single daily dose.

How long to use it

Continue taking *Lisinopril* for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

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 following effects are most likely to happen: Dizziness, palpitations.

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Lisinopril*.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Lisinopril* to anyone else, even if they have the same symptoms or condition as you.

Drinking alcohol can further lower your blood pressure and may increase certain side effects of *Lisinopril*.

Do not use salt substitutes or potassium supplements while taking *Lisinopril*, unless your doctor has told you to. Avoid getting up too fast from a sitting or lying position, or you may feel dizzy. Get up slowly and steady yourself to prevent a fall.

Things to be careful of

Driving and using machines

Some people feel dizzy or tired when taking this medicine. If this happens to you, do not drive or use any tools or machines.

You must wait to see how your medicine affects you before trying these activities.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Get emergency medical help if you have any of these signs of an allergic reaction to *Lisinopril*: hives; severe stomach pain, difficult breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have a serious side effect such as:

- feeling like you might pass out
- urinating less than usual or not at all
- swelling, rapid weight gain
- fever, chills, body aches, flu symptoms
- tired feeling, muscle weakness, and pounding or uneven heartbeats
- Chest pain; or high potassium (slow heart rate, weak pulse, muscle weakness, tingly feeling).

Less serious *Lisinopril* side effects may include:

- cough
- dizziness, drowsiness, headache
- depressed mood
- nausea, vomiting, diarrhea, upset stomach
- mild skin itching or rash.

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).

Storage and Disposal of *Lisinopril*

Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

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.

Product Description

What it looks like

Lisinopril tablet 5mg: White biconvex, capsule shaped tablets with breakline on one side and 'LIPRIL' inscription on other side

Lisinopril tablet 10mg: Reddish-brown, biconvex capsule shaped tablet with a break line on one side and LIPRIL inscription on the other side.

Ingredients

- Active ingredient
Lisinopril
- Inactive ingredients
Lactose monohydrate, Corn Starch, Povidone, colour iron oxide (only for Lisinopril tablet 10mg), Isopropyl alcohol, Magnesium Stearate, Talc

MAL numbers:

Lisinopril tablet 5mg: MAL19973617A
Lisinopril tablet 10mg: MAL19973618A

Manufacturer

Lupin Limited,
A-28/1, M.I.D.C,
Chikalthana,
Aurangabad – 431 210,
INDIA

Product Registration Holder

Pahang Pharmacy Sdn. Bhd
Lot 5979, Jalan Teratai,
5 1/2 Mile Off Jalan Meru
41050 Klang
Selangor, MALAYSIA.

Date of revision

28/11/2013