

APO-Lisinopril Tablets

Contains the active ingredient lisinopril (as lisinopril dihydrate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about lisinopril. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Lisinopril. It contains the active ingredient lisinopril (as lisinopril dihydrate).

It is used to treat the following:

- People with mild or moderate hypertension (high blood pressure)
- People with congestive heart failure
- People with acute myocardial infarction (heart attack)

High Blood Pressure

Everyone has blood pressure. This pressure helps get your blood all around your body.

Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

People with high blood pressure often feel fine and have no symptoms. You can only tell if you have high blood pressure by having your blood pressure regularly checked. If high blood pressure is not treated it can lead to serious health problems, including stroke, heart disease and kidney failure.

Lisinopril is used to lower high blood pressure (hypertension).

Congestive Heart Failure

Heart failure means that the heart

muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working.

Heart failure may start off with no symptoms, but as the condition progresses, people may feel short of breath or may get tired easily after light physical activity such as walking. Some people may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

Lisinopril may help to improve the symptoms of heart failure.

When used to treat heart failure, lisinopril is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney to get rid of excess fluid from the body.

Heart Attack

A heart attack occurs when one of the major blood vessels supplying blood to the heart muscle becomes blocked. As a result of the blockage, the heart does not receive the oxygen it needs and the heart muscle becomes damaged. This may lead to further complications such as heart failure, irregular heart rhythms and blood clots.

In some patients, lisinopril may help to prevent some of the further complications of heart attack, such as heart failure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your

doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

Lisinopril belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors.

It widens the blood vessels so that blood can pass through them more easily. This means that your blood pressure will drop, and it also means that if you have heart failure your heart can cope with doing some exercise and you won't run out of breath as easily.

Lisinopril also helps prevent complications which follow a heart attack, such as heart failure.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

You have or have had any of the following:

- renal artery stenosis (a problem with the blood vessels to one or both kidneys).
- renal dialysis using polyacrylonitrile high flux membranes.
- You are taking the following medications:
 - aliskiren-containing medicines in patients with diabetes
 - aliskiren-containing medicines in patients with moderate to severe kidney problems

You are pregnant.

Lisinopril may affect your developing baby if you take it during pregnancy.

You have had an allergic reaction to lisinopril or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

You have had a reaction to other types of ACE inhibitors which made your face, lips, tongue, throat, hands or feet swell up, or you had trouble breathing.

If you have had this type of allergic reaction to another ACE inhibitor you may have the same reaction to lisinopril.

You have previously had swollen face, lips, tongue, throat, hands or feet or breathlessness, for no apparent reason (a rare allergic condition known as angio-oedema).

The expiry date (EXP) printed on the pack has passed.

The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems, or you are having dialysis
 - diabetes
 - liver problems
 - heart problems

- cerebrovascular disease (which affects blood flow to the brain)
 - low blood pressure (you may notice this as faintness or dizziness, especially when standing)
 - recent diarrhoea or vomiting
 - low levels of sodium, or high levels of potassium in your blood
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
 4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have surgery or a general anaesthetic.
 6. You are following a very low salt diet.
 7. You are having desensitisation treatment or have had an allergic reaction during previous desensitisation treatment (e.g. treatments using bee, wasp or ant venom).
 8. You are currently receiving or are planning to receive dental treatment.
 9. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with lisinopril. These include:

- other medicines used for treating high blood pressure
- diuretics (fluid, or water tablets)
- potassium- sparing diuretics such as spironolactone, eplerenone, triamterene and amiloride
- potassium tablets or potassium-containing salt substitutes
- lithium, used for mood swings and depression
- medicines to relieve pain, swelling and other symptoms of inflammation, including arthritis, such as gold therapy, Non-

Steroidal Anti-inflammatory Drugs (NSAIDs) (e.g. indomethacin) or COX-2 inhibitors (e.g. Celebrex). It is especially important to tell your doctor when taking blood pressure, water and/or heart tablets together with NSAIDs or COX-2 inhibitors and lisinopril.

- tablets or injections used for treating diabetes. Your blood glucose levels should be closely monitored whilst taking lisinopril, especially during the first month.
- general anaesthetics

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with lisinopril.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines. If you need to take 2.5 mg then you must use a different brand of lisinopril, as the 5 mg tablets must not be broken in half to give a 2.5 mg dose.

High blood pressure

Most people start with 5 to 10 mg per day (although some may have less). The doctor will monitor your blood pressure and will gradually increase the dose of lisinopril if necessary. Most patients take between 10 and 20 mg once each day.

Heart Failure

The usual starting dose is 2.5 mg, taken once a day.

Depending on your response, this dose may need to be gradually increased.

The usual dose is 5 to 20 mg each day, taken once a day.

Heart Attack

You may start taking lisinopril within 24 hours of the start of a heart attack, and continue taking it for six weeks or more.

The usual starting dose is 5 mg, followed by 5 mg 24 hours later. Then 10 mg is taken 48 hours later, and once every day after that.

Some patients may have lower doses.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow your tablets with a glass of water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Lisinopril can help control blood pressure, improve heart failure and prevent complications of heart attack, but it cannot cure them. Therefore you will need to take this medicine every day.

Continue taking your medicine for as long as your doctor tells you.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for missed doses.

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much lisinopril, you may feel dizzy or light-headed, or you may faint.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breast-feeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital. Your blood pressure may drop suddenly during a general anaesthetic.
- you have diarrhoea or vomiting. This may lead to dehydration, and your blood pressure may drop too much.

Your doctor will do regular blood tests and may occasionally do other

tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell your doctor immediately if you feel light-headed, dizzy or faint, after taking your first dose of lisinopril, or after your dose is increased.

This is especially important if you are taking lisinopril for heart failure.

To avoid feeling light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

This feeling may be because your blood pressure is falling suddenly, especially if you are also taking a diuretic (water) tablet. Standing up slowly from a lying or sitting position will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, tell your doctor.

Drink plenty of water during exercise and hot weather, especially if you sweat a lot.

If you become dehydrated your blood pressure may drop too much and you may feel light-headed or sick. If you continue to feel unwell, see your doctor.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery or doing any other dangerous activity until you know how this medicine affects you.

Lisinopril may cause dizziness or light-headedness in some people, which may affect their reaction times. This is more likely to happen after the first dose or after increasing the dose.

Make sure you know how you react to lisinopril before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs, avoid the above activities.

If you drink alcohol, the dizziness or light-headedness may be worse.

Things that would be helpful for your blood pressure or heart failure

Some self-help measures suggested below may help your condition.

Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol**
Your doctor may advise you to limit your alcohol intake.
- **Diet**
Eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- **Exercise**
Regular exercise helps to reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme for you.
- **Smoking**
Your doctor may advise you to stop smoking or at least cut down.
- **Weight**
Your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking lisinopril or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- headache
- dizziness
- fatigue, weakness
- a persistent, dry cough
- mild stomach upsets such as feeling or being sick, indigestion, diarrhoea, constipation, wind or stomach pains

Other possible reactions include:

- flushing
- loss of appetite
- feeling sleepy or having problems going to sleep, strange dreams
- hair loss or thinning
- changes in the way things taste or smell
- blurred vision
- gout
- flu-like symptoms
- blocked or runny nose or sinus pain.
- muscle, joint, back, neck, leg or shoulder pain
- skin problems including itchiness, rash, or painful areas
- sunburn-type rash following short exposure to the sun
- psoriasis and other serious skin conditions

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- light-headedness or dizziness, especially during the first few days of taking lisinopril
- changes in the way your heart beats, for example, if you notice it beating faster
- chest pain

- difficulty breathing, wheezing
- feeling confused, anxious or depressed
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- bruising more easily than normal
- severe abdominal pain
- high or low blood sugar levels
- weakness, tingling or numbness of the hands or feet
- passing urine more or less than is normal for you; burning feeling when urinating, kidney pain, blood in the urine or cloudy urine
- signs of dehydration such as dry mouth, muscle cramps, headache, nausea, vomiting, drowsiness, irritability and tiredness. This may be caused by vomiting, diarrhoea, excessive perspiration or not enough water. If untreated, mental confusion and fits may develop. Your doctor may need to monitor your blood sodium levels.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and are usually very rare. You may need urgent medical attention or hospitalisation.

- swelling of the hands, feet, ankles, face, lips, mouth or throat, difficulty in swallowing or breathing
- fainting, especially during the first few days of taking lisinopril
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- yellowing of the skin and/or eyes, also called jaundice
- severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to lisinopril, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink.

Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can

dispose of the remaining medicine safely.

Product description

What APO-Lisinopril Tablets look like

Lisinopril 5 mg tablets:

Light pink coloured, circular, biconvex, uncoated tablets with "5" embossed and break line on one side and "BL" embossing on other side.

Lisinopril 10 mg tablets:

Light pink coloured, circular, biconvex, uncoated tablets with "10" embossed on one side and "BL" embossing on other side.

Lisinopril 20 mg tablets:

Pink coloured, circular, biconvex, uncoated tablets with "20" embossed on one side and "BL" embossing on other side.

Alternative lisinopril products should be used if a 2.5 mg dose is required. The 5 mg tablets must not be broken in half to give a 2.5 mg dose.

Ingredients

Each tablet contains 5, 10 or 20 mg of lisinopril, present as lisinopril dihydrate, as the active ingredient.

It also contains the following inactive ingredients:

- calcium hydrogen phosphate dihydrate
- Mannitol
- maize starch
- magnesium stearate
- iron oxide red.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Lisinopril 5 mg tablets:

PVC/Al blister packs of 10, 14, 28, 30, 50, 56, 84 and 100 tablets. AUST R 213393.

APO-Lisinopril 10 mg tablets:

PVC/Al blister packs of 10, 14, 28, 30, 50, 56, 84 and 100 tablets. AUST R 213394.

APO-Lisinopril 20 mg tablets:

PVC/Al Blister packs of 10, 14, 28, 30, 50, 56, 84 and 100 tablets. AUST R 213395.

*Not all strengths or pack sizes may be available

Sponsor

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