

ZINOPRIL®

lisinopril (as dihydrate)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZINOPRIL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

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

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What ZINOPRIL is used for

ZINOPRIL lowers high blood pressure, called hypertension. It is also used to treat heart failure and patients who have just had a heart attack.

Hypertension:

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. There are usually no symptoms of hypertension. The only way of knowing that you have hypertension

is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure.

ZINOPRIL helps to lower your blood pressure.

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, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients 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.

ZINOPRIL helps to treat heart failure and may improve your symptoms. One of the ways ZINOPRIL helps heart failure is that it widens the blood vessels, so that the heart does not have to pump as hard to move the blood around the body. This also means that when you place extra demands on your heart, such as during exercise, the heart may cope better so you may not get short of breath as easily.

When used to treat heart failure, ZINOPRIL 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 is damaged. This damage may lead to further complications such as heart failure, irregular heart rhythms and blood clots.

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

ZINOPRIL belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

Your doctor may prescribe ZINOPRIL for another reason. Ask your doctor if you have any questions about why ZINOPRIL has been prescribed for you.

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

ZINOPRIL is not addictive.

Before you take ZINOPRIL

When you must not take it

Do not take ZINOPRIL if:

- **you have taken any medicines called 'ACE-inhibitors' before and have had allergic reactions with swelling of the hands, feet, or ankles, the face, lips, tongue and/or throat with difficulty in swallowing or breathing or if you or a**

member of your family have had a similar reaction

- If you or a family member has had an allergic reaction to an ACE inhibitor before, you may be allergic to ZINOPRIL

- you have an allergy to lisinopril (the active ingredient in ZINOPRIL) or any of the ingredients in ZINOPRIL listed at the end of this leaflet

Some of the symptoms of an allergic reaction to ZINOPRIL may include skin rash, itchiness, difficulty breathing or swallowing, or swelling of the face, lips, tongue or throat.

- you are pregnant or breast-feeding

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

- you or a member of your family has a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason

- you are undergoing haemodialysis

- you are taking a blood pressure medicine containing aliskiren and you have diabetes mellitus

- you are taking a blood pressure medicine containing aliskiren and you have kidney problems

Do not take ZINOPRIL after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal. If you are not sure whether you should start taking ZINOPRIL, talk to your doctor.

Before you start to take it

Tell your doctor if you have any allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- kidney problems or are undergoing dialysis
- low blood pressure (you may notice this as faintness or dizziness, especially when standing)
- liver problems
- diabetes
- aortic stenosis (narrowing of the aorta), renal stenosis (narrowing of the renal artery) or hypertrophic cardiomyopathy (an increase in the thickness of the heart muscle)
- diarrhoea or vomiting
- any other medical condition.

Tell your doctor if you are following a very low salt diet.

Tell your doctor if you are going to receive desensitization treatment for an allergy, e.g., insect stings etc.

The desensitisation treatment reduces the effects of the allergy (e.g. honey bee or wasp stings) but sometimes it can cause a more severe allergic reaction if you are taking an ACE inhibitor during the desensitisation treatment.

Tell your doctor if you are taking medicines called mTOR inhibitors (such as temsirolimus, everolimus, sirolimus) or medicines containing NEP inhibitors (such as racecadotril).

Taking these medicines with ZINOPRIL may increase the risk of angioedema.

Signs of angioedema include swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing.

Tell your doctor if you are pregnant or intend to become pregnant.

ZINOPRIL is not recommended for use during pregnancy.

Tell your doctor if you are breastfeeding or plan to breastfeed.

ZINOPRIL should not be used while breastfeeding or if planning to breastfeed.

If you have not told your doctor about any of the above, tell him/her before you start taking ZINOPRIL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and ZINOPRIL may interfere with each other.

These include:

- medicines used to treat high blood pressure or heart problems called angiotensin II receptor blockers, such as candesartan, valdesartan, telmisartan, olmesartan or irbesartan.
- other medicines used to treat high blood pressure including any that contain aliskiren (see also information under the heading "When you must not take it")
- diuretic tablets - also called fluid or water tablets
- lithium, a medicine used to treat some types of mental disorders
- potassium tablets, salt substitutes containing potassium or other medicines which can increase potassium in your body.
- non-steroidal anti-inflammatory medicines used to treat arthritis and muscle pain, such as indometacin, naproxen or ibuprofen
- heparin, a medicine used to prevent blood clots
- a medicine used to treat infection containing sulfamethoxazole and trimethoprim, also known as co-trimoxazole
- gold injections (such as sodium aurothiomalate) usually used to treat rheumatoid arthritis

- insulin or other medicines used to treat diabetes (e.g. vildagliptin)
- medicines used to break down blood clots such as alteplase or reteplase
- medicines called mTOR inhibitors (such as temsirolimus, everolimus, sirolimus or medicines containing NEP inhibitors (such as racecadotril). (See also information under the heading "Before you start to take it")

These medicines may be affected by ZINOPRIL or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

If you have not told your doctor about any of the above, tell them before you take any ZINOPRIL.

How to take ZINOPRIL

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 box, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines.

Take ZINOPRIL only when prescribed by your doctor.

For high blood pressure:

For most patients, the usual starting dose is 5 mg to 10 mg taken once a day.

Some patients may need a lower starting dose. The dose may need to be increased depending on your blood pressure.

Most patients take between 10 mg to 20 mg each day, taken once a day.

For heart failure:

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

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

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

For heart attack:

ZINOPRIL may be started within 24 hours of the onset of the symptoms of heart attack. The usual starting dose is 5 mg, which is followed 24 hours later by another 5 mg dose.

This is then followed 48 hours later by a 10 mg dose, and then 10 mg taken once a day thereafter. Some patients may need a lower starting and maintenance dose.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How to take it

Swallow the tablets whole with a full glass of water or other fluid.

Do not crush or chew the tablets.

When to take it

ZINOPRIL is usually taken once a day.

Take your ZINOPRIL at about the same time each day.

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

It does not matter if you take ZINOPRIL before or after food.

How long to take it

Continue taking ZINOPRIL for as long as your doctor tells you to.

ZINOPRIL helps control your high blood pressure and helps improve your heart failure but does not cure it. Therefore, ZINOPRIL must be taken every day. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

If you have trouble remembering your dose, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ZINOPRIL. Do this even if there are no signs of discomfort or poisoning.

If you take too many tablets you will probably feel light-headed or dizzy, or you may faint.

You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking ZINOPRIL

Things you must do

Have your blood pressure checked when your doctor says to make sure ZINOPRIL is working.

Tell your doctor immediately if you feel any light-headedness or dizziness after you take your first dose of ZINOPRIL or if your dose is increased.

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

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy, especially if you are also taking a diuretic (fluid tablet). This is because your blood pressure is falling suddenly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

If you become pregnant while taking ZINOPRIL, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking ZINOPRIL.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking ZINOPRIL.

Your blood pressure may drop suddenly during surgery.

Make sure you drink enough water during exercise and hot weather when you are taking ZINOPRIL, especially if you sweat a lot.

If you do not drink enough water while taking ZINOPRIL, you may faint or feel light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you have excessive vomiting and/ or diarrhoea while taking ZINOPRIL, tell your doctor.

This can result in you losing too much water and may drop your blood pressure too much.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium level in the blood and see how your kidneys are working.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not stop taking ZINOPRIL or change the dose without first checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Do not let yourself run out of medicine over the weekend or on holidays.

Do not give ZINOPRIL to anyone else even if they have the same condition as you.

Do not use ZINOPRIL to treat other complaints unless your doctor says to.

Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

Things to be careful of

Be careful driving or operating machinery until you know how ZINOPRIL affects you.

This medicine may cause dizziness (light-headedness) or tiredness in some people, especially after the first dose or if the dose is increased.

Make sure you know how you react to ZINOPRIL before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, 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.
- Salt - your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake, you should avoid using salt in cooking or at the table.
- 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. Know warning signs of heart attack and what to do:
- Tightness, fullness, pressure, squeezing, heaviness or pain in

- your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).

If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZINOPRIL

This medicine helps most people with heart failure or hypertension, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- light-headedness or dizziness
- headache
- mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
- hair loss or thinning
- impotence
- fatigue
- nausea
- dry cough
- skin rashes
- changes in the way things taste

- feeling sleepy or difficulty in going to sleep, strange dreams
- running nose or sinus pain
- changes in the way things smell

The above list includes the more common side effects of your medicine. They are usually mild and short-lived but may be serious.

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

- changes in the way your heart beats, for example if you notice it beating faster
- itchy skin rash, psoriasis or other skin problems
- sign of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- tingling or numbness of the hands and feet
- passing less urine than is normal for you
- bruising more easily than normal
- severe abdominal pain
- yellowing of the skin and/or eyes, also called jaundice
- signs of dehydration such as nausea, vomiting, muscle cramps, headache, drowsiness and tiredness
- seeing, feeling or hearing things that are not there

The above list includes serious side effects that may require medical attention. Serious side are rare.

If any of the following happen, stop taking ZINOPRIL and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- chest pain, angina
- swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing
- wheeziness due to tightness in the chest, difficulty breathing
- collapse, numbness or weakness of arms or legs

- pinkish, itchy swellings on the skin also called hives or nettle rash
- fainting

The above list includes very serious side effects. If you have them you may have had a serious allergic reaction to ZINOPRIL. You may need urgent medical attention or hospitalisation. These side effects are very rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

After using ZINOPRIL

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep ZINOPRIL in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep ZINOPRIL 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 ZINOPRIL, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

ZINOPRIL comes in 5 mg, 10 mg and 20 mg tablet strengths.

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

10 mg: light pink coloured, circular, biconvex, uncoated tablets with "10" embossing on one side and "BL" embossing on the other side.

20 mg: pink coloured, circular, biconvex, uncoated tablets with "20" embossing on one side and "BL" embossing on the other side.

ZINOPRIL comes in pack sizes of 28 tablets.

Ingredients

Active ingredient:

Lisinopril dihydrate

Inactive ingredients:

- calcium hydrogen phosphate dihydrate
- Mannitol
- Maize Starch
- Magnesium Stearate
- Iron Oxide Red

Supplier

ZINOPRIL is supplied in Australia by:

Alphapharm Pty Limited trading as Viatris

Level 1, 30 The Bond
30 - 34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

Australian registration numbers:

ZINOPRIL 5 mg:
AUST R 152716

ZINOPRIL 10 mg:
AUST R 152717

ZINOPRIL 20 mg:
AUST R 152718

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