

# ZINOPRIL®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### 1. Why am I taking ZINOPRIL?

ZINOPRIL contains the active ingredient lisinopril. ZINOPRIL is used to lower high blood pressure, which doctors call hypertension. It is also used to treat heart failure and patients who have just had a heart attack. For more information, see Section [1. Why am I taking ZINOPRIL?](#) in the full CMI.

### 2. What should I know before I take ZINOPRIL?

Do not use if you have ever had an allergic reaction to lisinopril or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section [2. What should I know before I take ZINOPRIL?](#) in the full CMI.

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### 3. What if I am taking other medicines?

Some medicines may interfere with ZINOPRIL and affect how it works. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take ZINOPRIL?

- Take ZINOPRIL as prescribed by your doctor. This depends on your condition and whether you are taking other medicines.

More instructions can be found in Section [4. How do I take ZINOPRIL?](#) in the full CMI.

### 5. What should I know while taking ZINOPRIL?

#### Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking ZINOPRIL.
- Have your blood pressure checked when your doctor says to make sure ZINOPRIL is working.
- **Call your doctor straight away if you:** feel any light-headedness or

	<p>dizziness, become pregnant, have excessive vomiting and/or diarrhoea while taking ZINOPRIL.</p> <ul style="list-style-type: none"> <li>• Make sure you drink enough water during exercise and hot weather when you are taking ZINOPRIL.</li> <li>• Go to your doctor regularly for a check-up.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take ZINOPRIL to treat any other complaints unless your doctor tells you to.</li> <li>• Do not give ZINOPRIL to anyone else, even if they have the same condition as you.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how ZINOPRIL affects you.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Your doctor may advise you to limit your alcohol intake.</li> </ul>

<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C.</li><li>• Store in a cool, dry place, away from children.</li></ul>
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For more information, see Section [5. What should I know while taking ZINOPRIL?](#) in the full CMI.

## 6. Are there any side effects?

There are a number of side effects associated with this medicine. It is important to be aware of them so that you can identify any symptoms if they occur (see full CMI for more details). **Less serious side effects:** mild stomach upsets, sinus pain, headache, fatigue, feeling sleepy or difficulty in going to sleep, strange dreams.

**Serious side effects:** heart beats changes, passing less urine, yellowing of the skin and/or eyes, bruising easily, severe abdominal pain, hallucinations, itchy skin rash, tingling or numbness of hands or feet. **Very serious side effects:** chest pain, angina, swelling of the face, lips, mouth, tongue or throat, wheeziness, difficulty breathing, collapse, numbness/weakness of arms or legs, hives, fainting. **This is not a complete list of side effects.** For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ZINOPRIL®

**Active ingredient(s):** lisinopril

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking ZINOPRIL. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ZINOPRIL.**

**Where to find information in this leaflet:**

- [1. Why am I taking ZINOPRIL?](#)
- [2. What should I know before I take ZINOPRIL?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take ZINOPRIL?](#)
- [5. What should I know while taking ZINOPRIL?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking ZINOPRIL?

**ZINOPRIL contains the active ingredient lisinopril.** ZINOPRIL belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

**ZINOPRIL is used to lower high blood pressure, which doctors call 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.

## **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.

## 2. What should I know before I take ZINOPRIL?

### Warnings

#### Do not take ZINOPRIL if:

- you are allergic to lisinopril, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can take this medicine.
- 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.
  - you or a family member has had an allergic reaction to an ACE inhibitor before, you may be allergic to ZINOPRIL.
- you or a family member has a strong history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.
  - 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 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

## **Check with your doctor if you:**

- have any other medical conditions including:
  - 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
- take any medicines for any other condition
- are following a very low salt diet
- are going to receive desensitisation treatment for an allergy, e.g. to insect stings
  - The desensitisation treatment reduces the effects of the allergy (e.g. 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.
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

ZINOPRIL is not recommended for use during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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

## **3. What if I am taking other medicines?**

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

**Some medicines may interfere with ZINOPRIL and affect how it works, and some medicines may be affected by ZINOPRIL. 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 indomethacin, naproxen and 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
- 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).

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.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZINOPRIL.**

## **4. How do I take ZINOPRIL?**

### **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. Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.
- 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 high blood pressure.
  - Most patients take 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 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.

## **How long to take ZINOPRIL**

- Continue taking the tablets for as long as your doctor tells you.
- ZINOPRIL helps control your high blood pressure and helps improve your heart failure, but does not cure it.
- Follow the instructions provided and take ZINOPRIL until your doctor tells you to stop.

## **When to take ZINOPRIL**

- ZINOPRIL should be taken at about the same time each day. Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

## **How to take ZINOPRIL**

- Swallow ZINOPRIL with a glass of water or other liquid.
- Do not crush or chew tablets.
- It does not matter if you take ZINOPRIL before or after food.

## **If you forget to take ZINOPRIL**

ZINOPRIL should be taken regularly at the same time each day.

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

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

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

## **If you take too much ZINOPRIL**

If you think that you have taken too much ZINOPRIL, you may need urgent medical attention. If you take too many tablets you will probably feel light-headed or dizzy or may faint.

**You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while taking ZINOPRIL?**

### **Things you should do**

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

### **Call your doctor straight away if you:**

- feel any light-headedness or dizziness after you take your first dose of ZINOPRIL
  - This is especially important if you are taking ZINOPRIL for heart failure
- feel light-headed, dizzy or faint, and this problem gets worse or continues
  - Get up slowly when getting out of bed or standing up.
  - You may feel light-headed or dizzy, especially if you are 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.

- become pregnant while taking ZINOPRIL
- are about to be started on any new medicine
- plan to have surgery (even at the dentist) that needs a general anesthetic
  - Your blood pressure may drop suddenly during surgery
- have excessive vomiting and/or diarrhoea while taking ZINOPRIL
  - This can result in losing too much water and may drop your blood pressure too much

## **Things you must do**

- 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.
- 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 test, tell your doctor that you are taking this medicine.
  - It may interfere with the results of some tests.

Remind any doctor, dentist or pharmacist you visit that you are taking ZINOPRIL.



## Things you should 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 completely.
- Do not take ZINOPRIL to treat any other complaints unless your doctor tells you to.
- Do not give ZINOPRIL to anyone else, even if they have the same condition as you.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how ZINOPRIL affects you.**

ZINOPRIL may cause dizziness 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.

## **Drinking alcohol**

### **Tell your doctor if you drink alcohol.**

Your doctor may advise you to limit your alcohol intake.

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

Some self-help measures below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- Diet - eat a health 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.

## **Looking after your medicine**

- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place where the temperature stays below 25°C, away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### **Keep it where young children cannot reach it.**

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

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date or if the packaging is torn or shows signs of tampering.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Gut-related:</b></p> <ul style="list-style-type: none"><li>• mild stomach upsets such as feeling sick, diarrhoea, or stomach pains</li><li>• impotence</li><li>• nausea</li></ul> <p><b>Respiratory or breathing-related:</b></p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dry cough</li> <li>● running nose or sinus pain</li> <li>● changes in the way things smell</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>● light-headedness or dizziness</li> <li>● headache</li> <li>● fatigue</li> <li>● hair loss or thinning</li> <li>● changes in the way things taste</li> <li>● feeling sleepy or difficulty in going to sleep, strange dreams</li> </ul>	

### **Serious side effect**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction-related:</b></p> <ul style="list-style-type: none"> <li>● changes in the way your heart beats, for example, if you notice it beating faster</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● yellowing of the skin and/or eyes, also called jaundice</li> <li>● tingling or numbness of the hands and feet</li> <li>● severe abdominal pain</li> </ul> <p><b>Skin-related:</b></p> <ul style="list-style-type: none"> <li>● itchy skin rash, psoriasis or other skin problems</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>● signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers</li> <li>● passing less urine than is normal for you</li> <li>● bruising more easily than normal</li> <li>● severe abdominal pain</li> <li>● signs of dehydration such as nausea, vomiting, muscle cramps, headache, drowsiness and tiredness</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● seeing, feeling or hearing things that are not there</li> </ul>	

## Very serious side effects

<b>Very serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction-related:</b></p> <ul style="list-style-type: none"> <li>● chest pain, angina</li> <li>● swelling of the face, lips, mouth, tongue or throat, which may cause difficulty in swallowing or breathing</li> <li>● wheeziness due to tightness in the chest, difficulty breathing</li> <li>● collapse, numbness or weakness of arms or legs</li> <li>● pinkish, itchy swellings of the skin, also called hives or nettle rash</li> <li>● fainting</li> </ul>	<p><b>Stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital.</b></p>

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

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

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

ZINOPRIL is not addictive.

### **What ZINOPRIL contains**

<b>Active ingredient</b>	Lisinopril
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	Mannitol Calcium hydrogen phosphate dihydrate Maize starch Magnesium stearate Iron oxide red

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What ZINOPRIL looks like**

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

ZINOPRIL 5 mg: light pink coloured, circular, biconvex, uncoated tablets with "5" debossing and break line on one side and "BL" debossing on the other side.

AUST R 152716

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

AUST R 152717

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

AUST R 152718

ZINOPRIL comes in pack sizes of 28 tablets.

## **Who distributes ZINOPRIL**

ZINOPRIL is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

This leaflet was prepared in June 2024.

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