

# AURO-LISINOPRIL 5, 10 & 20

*Lisinopril*

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## Consumer Medicine Information

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### WHAT IS IN THIS LEAFLET

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This leaflet answers some common questions about AURO-LISINOPRIL. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

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

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.** You may need to read it again.

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### WHAT AURO-LISINOPRIL IS USED FOR

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AURO-LISINOPRIL lowers high blood pressure, called hypertension. It is also used to treat heart failure and patients who have just had a heart attack. Lisinopril belongs to a group of medicines called ACE inhibitors.

#### **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.

AURO-LISINOPRIL 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.

AURO-LISINOPRIL helps to treat heart failure and may improve your symptoms.

One of the ways AURO-LISINOPRIL 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, AURO-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 is damaged. This damage may lead to further complications such as heart failure, irregular heart rhythms and blood clots.

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

AURO-LISINOPRIL belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

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

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## BEFORE YOU TAKE AURO-LISINOPRIL

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*Do not take AURO-LISINOPRIL if:*

**You have taken any medicines called 'ACE-inhibitors' for high blood pressure or heart failure before, which caused your face, lips, tongue, throat, hands or feet to swell up, or made it hard for you to breathe.**

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to AURO-LISINOPRIL.

**If you have an allergy to lisinopril or any of the ingredients in AURO-LISINOPRIL TABLETS listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction to AURO-LISINOPRIL 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.

**The tablets show visible signs of deterioration.**

You have a history of the swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.

If you are undergoing haemodialysis.

The package is torn or shows signs of tampering.

If you are not sure whether you should start taking AURO-LISINOPRIL, talk to your doctor.

The expiry date (EXP) printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

*Before you start to take it*

**Tell your doctor:**

**1. If you intend to become pregnant or intend to breast-feed**

**If you suffer from:**

- Kidney disease or are undergoing dialysis
- Low blood pressure
- Liver disease
- Aortic stenosis or hypertrophic cardiomyopathy
- Diabetes
- Any other medical condition

**2. If you are taking any other medicines, including any that you bought from a pharmacy, supermarket or health food shop.**

Some of the medicines in common use that may interfere with AURO-LISINOPRIL include:

- Other medicines used to treat high blood pressure.
- Diuretic tablets.
- Lithium.
- Potassium tablets.
- Any non-steroidal anti-inflammatory medicines such as indomethacin.
- Dialyses with high-flux membranes (e.g. AN69).
- Antidiabetics (such as insulin or oral hypoglycaemic agents).
- Medicines containing gold

These medicines may be affected by AURO-LISINOPRIL, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking AURO-LISINOPRIL if you:

- 4. Have any allergies to lisinopril or any other ingredients in AURO-LISINOPRIL, or to any other medicines that you have used in the past, or to any other substances such as food, preservatives or dyes.**
- 5. Are following a very low-salt diet**

**6. Are going to receive desensitization treatment for an allergy, e.g., insect bites etc.**

**If you have not told your doctor about any of the above, tell them before you take any AURO-LISINOPRIL.**

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## HOW TO TAKE AURO-LISINOPRIL

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Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

### *How much to take*

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

**Take AURO-LISINOPRIL only when prescribed by your doctor.**

**For high blood pressure:**

For most patients, the usual starting dose is 5 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 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 5-20mg each day, taken once a day.

**For heart attack:**

AURO-LISINOPRIL 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 to take it*

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

### *When to take it*

AURO-LISINOPRIL is usually taken once a day.

Take your AURO-LISINOPRIL at about the same time each day.

It does not matter whether you take AURO-LISINOPRIL with food or not. Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take the tablets.

### *How long to take it*

AURO-LISINOPRIL helps control your high blood pressure and helps improve your heart failure, but does not cure it. Therefore AURO-LISINOPRIL must be taken every day. Continue taking AURO-LISINOPRIL as long as your doctor prescribes it.

### *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 it as you would normally.

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

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

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

### *In case of an overdose*

Immediately telephone your doctor or Poisons Information Center (telephone 131126) or go to the Accident or Emergency centers at the nearest hospital, if you think that you or anyone else may have taken too much AURO-LISINOPRIL. Do this even if there are no signs of discomfort or poisoning. Keep telephone numbers for these places handy.

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

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

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## WHILE YOU ARE USING AURO-LISINOPRIL

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### *Things you must do:*

#### **Have your blood pressure checked regularly.**

Drink plenty of water during exercise and hot weather while you are taking AURO-LISINOPRIL.

If you do not drink enough water while taking AURO-LISINOPRIL, 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.

**Tell your doctor immediately if you feel any light-headedness or dizziness after you take your first dose of AURO-LISINOPRIL or if your dose is increased. This is especially important if you are taking AURO-LISINOPRIL 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.

Be sure to keep all of your appointments with your doctor so that your progress can be monitored.

### **Tell all doctors, dentists and pharmacists who are treating you that you are taking AURO-LISINOPRIL if:**

- You become pregnant while taking AURO-LISINOPRIL.
- You are going to have any laboratory tests
- You about to be started on any new medicine
- You plan to have surgery that needs a general anaesthetic. Your blood pressure may drop suddenly during surgery.
- You feel the tablets are not helping your condition
- You have excessive vomiting and or diarrhoea while taking AURO-LISINOPRIL. This can result in you losing too much water and may drop your blood pressure too much.
- For any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

### **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.

### *Things you must not do*

Do not stop taking AURO-LISINOPRIL or change the dose without first checking with your doctor.

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

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

Do not use AURO-LISINOPRIL 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 AURO-LISINOPRIL affects you.

AURO-LISINOPRIL may cause dizziness (lightheadedness) or tiredness in some patients, especially after the first dose or if the dose is increased. Make sure you know how you react to AURO-LISINOPRIL 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 dietitian's help to lose weight.

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## SIDE EFFECTS

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### **Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking AURO-LISINOPRIL.**

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 these side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

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

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

- hypotension
- headache
- dizziness
- diarrhea or stomach pain
- fatigue
- nausea
- persistent dry cough
- skin rashes

- asthenia

These are usually mild side effects of AURO-LISINOPRIL, but may be serious.

### **Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:**

- Chest pain, angina
- Changes in the way your heart beats, for example if you notice it beating faster
- Difficulty breathing
- Wheeziness due to tightness in the chest
- Itchy skin rash 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
- Collapse numbness or weakness of arms or legs

These are all serious side effects. You may need urgent medical attention; however, these Serious side effects are rare.

### **If any of the following happens, stop taking AURO-LISINOPRIL and tell your doctor immediately or go to casualty at your nearest hospital.**

- Swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Pinkish, itchy swellings on the skin also called hives or nettle rash
- Fainting
- Yellowing of the skin and/or eyes, also called jaundice

These are very serious side effects. If you have them you may have had a serious allergic reaction to AURO-LISINOPRIL. You may need urgent medical attention or hospitalization. All of these side effects, however, are rare.

Also tell your doctor if you notice:

- Hair loss or thinning
- Impotence
- Psoriasis and other serious skin conditions
- 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

**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 if you notice anything else 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.

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

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## AFTER USING AURO-LISINOPRIL

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### *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 AURO-LISINOPRIL in a cool dry place where the temperature stays below 30°C.**

**Do not store it, or any other medicine, in a bathroom or near a sink.**

**Do not leave it in the car or on windowsills.**

Heat and dampness can destroy some medicines.

**Keep AURO-LISINOPRIL where young children cannot reach them.**

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

### *Disposal*

**If your doctor tells you to stop taking AURO-LISINOPRIL, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.**

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## PRODUCT DESCRIPTION

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### *Availability*

AURO-LISINOPRIL comes in 5 mg, 10 mg and 20 mg tablet strengths.

AURO-LISINOPRIL comes in pack sizes of 30.

- ***Auro-Lisinopril 5 (AUST R 148262)***  
Light red coloured, round shaped, biconvex, uncoated tablets, debossed with 'L' on one side and on other side with '5' on one side of the score line.
- ***Auro-Lisinopril 10 (AUST R 148274)***  
Light yellow coloured, round shaped, biconvex, uncoated tablets, debossed with 'L' on one side and on other side with '10'.
- ***Auro-Lisinopril 20 (AUST R 148275)***  
Light yellow coloured, capsule shaped, biconvex, uncoated tablets, debossed with 'L' on one side and on other side with '20'.

### *Ingredients*

#### *Active ingredient:*

Lisinopril dihydrate

#### *Inactive ingredients:*

- Calcium hydrogen phosphate anhydrous,
- Mannitol,
- Pregelatinised maize starch,
- Magnesium Stearate,
- Iron oxide red CI77491 (Auro-Lisinopril 5 only),
- Iron oxide yellow CI77492 (Auro-Lisinopril 10 and 20 only).

### *Name and Address of the Sponsor*

**Aurobindo Pharma Australia Pty Ltd**

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Business Park  
277-283 Lane Cove Road  
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Australia

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27 February 2009

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