

ZESTRIL®

Lisinopril dihydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about ZESTRIL. 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 ZESTRIL 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.

What ZESTRIL is used for

ZESTRIL lowers 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.

ZESTRIL 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.

ZESTRIL helps to treat heart failure and may improve your symptoms.

One of the ways ZESTRIL 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, ZESTRIL 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, ZESTRIL may help to prevent some complications of heart attack, such as heart failure.

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

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

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

ZESTRIL is not addictive.

Before you take ZESTRIL

When you must not take it

Do not take ZESTRIL 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 ZESTRIL.

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

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

- **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 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 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 ZESTRIL after the expiry date 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 ZESTRIL, talk to your doctor.

Before you start to take it

Tell your doctor if you have any allergies to:

- any other medicines

- any other substances such as foods, dyes or preservatives

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

- 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

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

Tell your doctor if you 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.

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 Zestril 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.

ZESTRIL is not recommended for use during pregnancy

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

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

Taking other medicines

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

Some medicines and ZESTRIL 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, valsartan, 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 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.

- 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 ZESTRIL, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor and pharmacist have more information about medicines to be careful with or avoid while taking ZESTRIL.

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

How to take ZESTRIL

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 ZESTRIL 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 20 mg each day, taken once a day.

For heart attack:

ZESTRIL 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

Take your ZESTRIL 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.

Swallow ZESTRIL with a glass of water or other liquid.

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

How long to take it

Continue taking the tablets for as long as your doctor tells you.

ZESTRIL helps control your high blood pressure and helps improve your heart failure, but does not cure it. Therefore, you must take ZESTRIL every day.

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 tablet(s) 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 that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone number 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much ZESTRIL. 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.

While you are using ZESTRIL

Things you must do

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

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

This is especially important if you are taking ZESTRIL 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 ZESTRIL, tell your doctor immediately.

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

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

Your blood pressure may drop suddenly during surgery.

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

If you do not drink enough water while taking ZESTRIL, 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 ZESTRIL, 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.

Things you must not do

Do not take ZESTRIL to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

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

ZESTRIL may cause dizziness (light-headedness) or tiredness in some patients, especially after the first dose or if the dose is increased. Make sure you know how you react

to ZESTRIL 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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking ZESTRIL.

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.

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:

- light-headedness or dizziness
 - headache
 - fatigue
 - dry cough
 - mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
 - hair loss or thinning
 - impotence
 - 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
- These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- changes in the way our heart beats, for example, if you notice it beating faster
- itchy skin rash, psoriasis or other skin problems
- signs 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

These are all serious side effects. You may need urgent medical attention.

If any of the following happen, stop taking ZESTRIL 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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZESTRIL. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking ZESTRIL

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 in a cool, dry place where the temperature stays below 30°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 windowsills.

Heat and dampness can destroy some medicines.

Keep your tablets in a safe place where children cannot see or reach them.

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 the tablets 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

ZESTRIL tablets are available in three strengths:

- ZESTRIL 5 mg are pink, round, biconvex tablets with a heart image and the figure 5 marked on one side and a line through the middle on the other side.
- ZESTRIL 10 mg are pink, round, biconvex tablets, with a heart image and the figure 10 marked on one side and are plain on the other side.
- ZESTRIL 20 mg are brownish-red, round, biconvex tablets with a heart image and the figure 20 marked on one side and are plain on the other side.

A box of ZESTRIL contains 30 tablets.

Ingredients

Active ingredient:

ZESTRIL 5 mg - 5 mg lisinopril per tablet

ZESTRIL 10 mg - 10 mg lisinopril per tablet

ZESTRIL 20 mg - 20 mg lisinopril per tablet

Inactive ingredients:

Each ZESTRIL tablet also contains the following inactive ingredients.

- mannitol
- calcium hydrogen phosphate dihydrate
- maize starch
- pregelatinised maize starch
- magnesium stearate (E572)
- iron oxide red C177491 (E172)

Manufacturer

ZESTRIL is supplied in Australia by

AstraZeneca Pty Ltd
 ABN 54 009 682 311
 66 Talavera Road
 MACQUARIE PARK NSW 2113

Telephone: 1800 805 342

The Australian Registration Numbers are:

ZESTRIL 5 mg - AUST R 70837
 ZESTRIL 10 mg - AUST R 70838
 ZESTRIL 20 mg - AUST R 70839

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