

# Lisinopril Sandoz

*lisinopril dihydrate tablets*

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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 Lisinopril Sandoz.

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 this medicine 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 Lisinopril Sandoz is used for

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This medicine is used to treat:

- high blood pressure (hypertension)
- heart failure
- patients who have just had a heart attack.

It contains the active ingredient lisinopril dihydrate.

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

It works by widening your blood vessels, which reduces pressure in the vessels. This makes it easier for your heart to pump blood around your body.

This also helps to increase the supply of oxygen to your heart, so

that when you place extra demands on your heart, such as exercise, your heart may cope better and you may not get short of breath as easily.

By making it easier for your heart to pump blood around your body and by increasing the supply of oxygen to your heart, Lisinopril Sandoz may reduce the risk of further damage to your heart after you have had a heart attack.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

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### Before you take Lisinopril Sandoz

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*When you must not take it*

**Do not take this medicine if you have or have had an allergy to:**

- lisinopril dihydrate, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product description
- any other similar medicines, called ACE inhibitors. Examples include perindopril (Coversyl®), ramipril (Tritace®) and enalapril (Renitec®).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

**Do not take this medicine if you have or have had a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.**

**Do not take this medicine if you are undergoing haemodialysis.**

You may be at increased risk of a severe allergic reaction when Lisinopril Sandoz is combined with some dialysis treatments.

**Do not take this medicine if you are pregnant.**

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

**Do not breastfeed if you are taking this medicine.**

The active ingredient in Lisinopril Sandoz may pass into breast milk and there is a possibility that your baby may be affected.

- 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 this medicine 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 this medicine, talk to your doctor.**

## *Before you start to take it*

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

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

- kidney problems, or are undergoing dialysis
- liver problems
- heart problems
- diabetes
- low blood pressure, which you may notice as dizziness or light-headedness, especially when standing
- any other medical conditions not listed in this leaflet.

**Tell your doctor if you intend to become pregnant or intend to breastfeed**

Lisinopril Sandoz should not be used during pregnancy or while breastfeeding.

**Tell your doctor if you:**

- have a family history of swelling of the face, lips, tongue, throat, hands or feet
- are following a very low salt diet. Low blood pressure may develop in people who are following a very low salt diet.
- have recently suffered from excessive vomiting or diarrhoea
- are about to receive desensitisation treatment for an allergy, e.g. to insect stings
- are scheduled to have surgery (including at the dentist) under general anaesthetic. Your blood pressure may drop suddenly.

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

## *Taking other medicines*

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

Some medicines and Lisinopril Sandoz may interfere with each other. These include:

- other medicines used to treat high blood pressure including any that contain aliskiren
- diuretic tablets, also known as fluid or water tablets, such as Lasix®, Urex® or Natrilix®
- lithium, a medicine used to treat mood swings and some types of depression
- potassium tablets such as Slow-K®, Span-K®, K-Mag® or Chlorvescent®
- potassium-containing salt substitutes such as Pressor K®
- any non-steroidal anti-inflammatory medicines (such as indomethacin)
- potassium-sparing agents such as spironolactone (Aldactone®), triamterene (Hydrene 25/50®) or amiloride (Moduretic®)
- gold therapy, used in the treatment of rheumatoid arthritis
- non-steroidal anti-inflammatory drugs (NSAIDs or COX-2 inhibitors), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis. Examples include aspirin, ibuprofen (Nurofen®) and celecoxib (Celebrex®).
- insulin or oral antidiabetic medicines. You should be closely monitored for low blood glucose (sugar) levels, especially during the first month of treatment with Lisinopril Sandoz.

These medicines may be affected by Lisinopril Sandoz 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.

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## How to take Lisinopril Sandoz

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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.

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

### *How much to take*

**Ask your doctor or pharmacist if you are unsure of the correct dose for you.**

They will tell you exactly how much to take.

**Follow the instructions they give you.**

If you take the wrong dose, Lisinopril Sandoz may not work as well and your condition may not improve.

**For high blood pressure (hypertension):**

The usual starting dose is 5 to 10mg 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 and 20mg each day, taken once a day.

**For heart failure:**

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

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

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

**For heart attack:**

Lisinopril Sandoz may be started within 24 hours of the onset of symptoms of heart attack. The usual starting dose is 5mg, which is followed 24 hours later by another 5mg dose. This is then followed 48 hours later by a 10mg dose, and then 10mg 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 full glass of water.

### *When to take Lisinopril Sandoz*

**Take your medicine 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.

### *How long to take Lisinopril Sandoz*

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### *If you forget to take it*

Take your dose as soon as you remember, and continue to take it as you would normally.

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 that you missed.**

This may increase the chance of you getting an unwanted side effect.

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

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

### *If you take too much (overdose)*

**Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764 766) 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 Lisinopril Sandoz. Do this even if there are**

**no signs of discomfort or poisoning.**

You may need urgent medical attention.

Symptoms of an overdose may include:

- light-headedness
- dizziness
- fainting.

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## While you are taking Lisinopril Sandoz

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### *Things you must do*

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Lisinopril Sandoz.**

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are going to have surgery (even at the dentist) that needs a general anaesthetic, tell the surgeon, dentist or anaesthetist that you are taking this medicine.**

Your blood pressure may drop suddenly during the surgery.

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

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

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

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

**If you experience excessive vomiting and/or diarrhoea while taking Lisinopril Sandoz, tell your doctor.**

You may lose too much water and salt and your blood pressure may drop too much.

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**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.**

Your doctor will need to check your blood pressure to make sure Lisinopril Sandoz is working.

Your doctor may do some blood tests from time to time to check your potassium levels and to see how your kidneys are working.

### *Things you must not do*

**Do not take Lisinopril Sandoz to treat any other complaints unless your doctor tells you to.**

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

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

### *Things to be careful of*

**Be careful driving or operating machinery until you know how Lisinopril Sandoz affects you.**

This medicine may cause dizziness, light-headedness and tiredness in some people, especially after the first dose or if the dose is increased. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

**Be careful when drinking alcohol while you are taking this medicine.**

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

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

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 continues or gets worse, talk to your doctor.

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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 Lisinopril Sandoz.**

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

**Do not be alarmed by the following lists 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
- tiredness
- dry cough
- muscle cramps
- mild stomach upsets such as feeling sick, diarrhoea or stomach pains
- hair loss or thinning
- psoriasis or other serious skin conditions
- inability to get or maintain an erection (impotence)
- difficulty sleeping (insomnia) or strange dreams
- changes in the way things taste or loss of taste.

These are usually mild side effects of the medicine, but some of them may be serious.

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

- fast or irregular heart beats
- blurred vision
- yellowing of the skin and/or eyes, also called jaundice
- itchy skin rash or other skin problems
- signs of frequent or worrying infections such as fever, mouth or tongue ulcers
- bruising more easily than normal
- signs of anaemia such as tiredness, being short of breath and looking pale
- tingling or numbness of the hands, feet or ankles
- passing less urine than is normal for you
- severe stomach pain
- changes in mood, confusion or depression.

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

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency 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
- chest pain or feeling of tightness, pressure or heaviness in the chest
- wheeziness due to tightness in the chest
- collapse, numbness or weakness in the arms or legs.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

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

Other side effects not listed above may also occur in some people.

Some side effects (for example changes in kidney or liver function, or low blood cell counts) can only be found when your doctor does tests from time to time to check your progress.

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## After taking Lisinopril Sandoz

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### *Storage*

Keep your medicine in the original container.

If you take the tablets out of its original container they may not keep well.

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

Do not store Lisinopril Sandoz 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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## Product description

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### *What it looks like*

Lisinopril Sandoz comes in three types of tablets:

Lisinopril Sandoz 5mg - round, biconvex, uniformly red, mottled tablets with a score notch on one side.

Lisinopril Sandoz 10mg - round, biconvex, uniformly red, mottled tablets with a score notch on one side.

Lisinopril Sandoz 20mg - round, biconvex, uniformly red, mottled tablets with a score notch on one side.

Available in blisters of 30 tablets.

### *Ingredients*

Active ingredients:

- Lisinopril Sandoz 5mg - 5mg lisinopril (as lisinopril dihydrate)
- Lisinopril Sandoz 10mg - 10mg lisinopril (as lisinopril dihydrate)
- Lisinopril Sandoz 20mg - 20mg lisinopril (as lisinopril dihydrate)

Inactive ingredients:

- calcium hydrogen phosphate dihydrate
- mannitol
- maize starch
- croscarmellose sodium
- magnesium stearate
- iron oxide red.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

### *Supplier*

Sandoz Pty Ltd  
ABN 60 075 449 553  
54 Waterloo Road,  
Macquarie Park, NSW 2113,  
Australia  
Tel: 1800 726 369

Novartis New Zealand Ltd  
PO Box 99102  
Newmarket, Auckland 1149  
New Zealand  
Tel: 0800 354 335

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### **Australian Register Numbers:**

Lisinopril Sandoz 5mg tablets:  
AUST R 158100

Lisinopril Sandoz 10mg tablets:  
AUST R 158101

Lisinopril Sandoz 20mg tablets:  
AUST R 158108