

# Captopril Sandoz®

*captopril dihydrate tablets*

## Consumer Medicine Information

### WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Captopril 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.

### WHAT CAPTOPRIL SANDOZ IS USED FOR

This medicine is used to treat:

- high blood pressure (hypertension)
- certain heart conditions
- certain kidney conditions associated with diabetes.

It contains the active ingredient captopril.

Captopril belongs to a group of medicines called angiotensin converting enzymes (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, and helps your kidneys work better.

**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.

### BEFORE YOU TAKE CAPTOPRIL SANDOZ

*When you must not take it*

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

- captopril, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other similar medicines such as 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 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 Captopril Sandoz may pass into breast milk and there is a possibility that your baby may be affected.

**Do not use this medicine in combination with aliskiren in patients with type 2 diabetes.**

Concomitant use of angiotensin-converting enzyme inhibitors (ACEIs)- including captopril with aliskiren is associated with an increased incidence of hypotension, hyperkalemia and changes in renal function.

**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, you have one kidney, or are undergoing dialysis. You may be at increased risk of a severe allergic reaction when Captopril Sandoz is combined with some dialysis treatments.
- liver problems

- heart problems
- cerebrovascular disease (disease of the blood vessels supplying blood to the brain)
- diabetes
- low blood pressure, which you may notice as dizziness or light-headedness, especially when standing
- neutropenia (low white blood cell count)
- collagen vascular diseases such as systemic lupus erythematosus or scleroderma
- any other medical conditions not listed in this leaflet.

**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 taking immunosuppressant medicines (medicines that lower your immune system)
- 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 Captopril 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 Captopril Sandoz may interfere with each other. These include:

- other medicines used to treat high blood pressure

- diuretic tablets, also known as fluid or water tablets, such as frusemide (Lasix®, Urex®) or indapamide (Natrlix®)
- any medicines used for angina, such as glyceryl trinitrate
- lithium, a medicine used to treat mood swings and some types of depression
- potassium tablets such as Duro-K®, Slow-K®, Span-K®, K-Mag®, K-Sol® or Chlorvescent®
- potassium-containing salt substitutes such as Pressor K®/potassium-sparing agents such as spironolactone (Aldactone®), triamterene (Hydrene 25/50®) or amiloride (Moduretic®)
- medicines which may increase potassium levels (e.g. heparin, trimethoprim/sulfamethoxazole)
- 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®)
- mammalian target of rapamycin inhibitors (e.g. temsirolimus, sirolimus, everolimus).

These medicines may be affected by Captopril 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 CAPTOPRIL 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, Captopril Sandoz may not work as well and your condition may not improve.

The usual dose ranges from 12.5mg to 50mg taken two or three times per day.

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

*How to take it*

Swallow the tablets whole with a full glass of water.

*When to take Captopril 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.

**Take your medicine on an empty stomach, for example, 1 hour before food.**

Food can interfere with the absorption of this medicine.

*How long to take Captopril 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 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 Captopril 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 or fainting.

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## WHILE YOU ARE TAKING CAPTOPRIL 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 Captopril 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 surgery.

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

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

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

If you do not drink enough water while you are taking Captopril 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 excess vomiting or diarrhoea while taking Captopril 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 Captopril 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 Captopril 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 Captopril 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 Captopril 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
- inability to get or maintain an erection (impotence)
- difficulty sleeping (insomnia) or strange dreams
- changes in the way things taste or loss of taste
- symptoms of hyperkalaemia (high levels of potassium in your body) such as confusion, irregular heartbeat, nervousness, numbness or tingling of the hands, feet or lips, shortness of breath or difficulty breathing, weakness or heaviness of the legs.

These are the more common side effects of the medicine.

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

- fast or irregular heart beats
- 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
- passing less urine than is normal for you
- 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.

The above list includes very serious side effects. 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 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 and 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 CAPTOPRIL SANDOZ

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### *Storage*

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Captopril 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*

Captopril Sandoz comes in three types of tablets:

Captopril Sandoz 12.5mg - round, white tablets with a score mark on one side.

Captopril Sandoz 25mg - round, cloverleaf shaped, white tablets with a crossed break mark on both sides.

Captopril Sandoz 50mg - round, cloverleaf shaped, white tablets with a crossed break mark on both sides.

Available in blisters of 90 tablets.

### *Ingredients*

Active ingredient:

- Captopril Sandoz 12.5mg - 12.5mg captopril
- Captopril Sandoz 25mg - 25mg captopril
- Captopril Sandoz 50mg - 50mg captopril.

Inactive ingredients:

- lactose
- microcrystalline cellulose
- maize starch
- stearic acid.

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

*Supplier/Distributor*

Sandoz Pty Ltd  
ABN 60 075 449 55354 Waterloo  
Road  
Macquarie Park, NSW 2113  
Australia  
Tel: 1800 726 369

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**Australian Register Numbers**

12.5mg tablets: AUST R 61419  
(blisters)

25mg tablets: AUST R 61416  
(blisters)

50mg tablets: AUST R 61420  
(blisters)