

Enalapril Sandoz®

enalapril maleate tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Enalapril 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 it is expected to 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 Enalapril Sandoz is used for

The name of your medicine is Enalapril Sandoz. It contains the active ingredient enalapril maleate.

Enalapril Sandoz is used to lower high blood pressure (hypertension). It is also used to treat heart failure.

Hypertension

Everyone has blood pressure. This pressure helps to circulate the 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. Enalapril Sandoz 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.

Enalapril Sandoz helps to treat heart failure, whether you have symptoms or not. In many patients with heart failure who have symptoms, Enalapril Sandoz may slow the progression of heart failure and reduce the need to go to hospital as a result of heart failure. Enalapril Sandoz may help some of these patients live longer.

In many patients with heart failure who have no symptoms, Enalapril Sandoz may help to stop the heart muscle from getting weaker. Enalapril Sandoz may also slow down the development of symptoms, such as shortness of

breath, tiredness after light physical activity, or swelling of the ankles and feet. These patients may be less likely to have hospital stays due to heart failure.

By taking Enalapril Sandoz, heart failure patients may have less chance of having a heart attack.

When used to treat heart failure, Enalapril Sandoz is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney get rid of excess fluid from the body.

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.

How Enalapril Sandoz works

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

One of the ways Enalapril Sandoz helps lower blood pressure and treat heart failure is that it widens your blood vessels, which reduces pressure in the vessels, making it easier for your heart to pump blood around your body. This helps increase the supply of oxygen to your heart, so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get short of breath as easily.

There is no evidence that Enalapril Sandoz is addictive.

Before you take Enalapril Sandoz

When you must not take it

Do not take this medicine if:

- you have an allergy to the active ingredient enalapril maleate, or to any of the other ingredients listed at the end of this leaflet under Product Description. Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty in breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin; muscle pain or tenderness or joint pain.
- you have taken any other 'ACE inhibitor' medicines 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.
- you have a history or a family history of swelling of the face, lips, tongue, throat, hands or feet for no apparent reason.
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.

Do not take this medicine if you are pregnant, plan on becoming pregnant or are 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.

Do not give this medicine to children.

The safety and effectiveness in children have not been established.

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, especially if they are in the same drug class as enalapril maleate
- any other substances, including foods, preservatives or dyes.

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

- kidney problems, or if you are undergoing dialysis treatment
- heart problems
- diabetes.

Tell your doctor if you have recently suffered from excessive vomiting or diarrhoea.

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

Tell your doctor if you are or intend to become pregnant or intend to breastfeed.

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

Tell your doctor if you suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing).

Tell your doctor if you plan to have surgery and anaesthesia (even at the dentist office) are scheduled, as there may be a sudden fall in blood pressure associated with anaesthesia.

If you have not told your doctor about any of the above, tell him/her before you start taking Enalapril 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 Enalapril Sandoz may interfere with each other. These include:

- other medicines used to treat high blood pressure

- diuretics, also known as fluid or water tablets
- non-steroidal anti-inflammatory drugs (NSAIDs or Coxibs/COX-2 inhibitors), medicines used to relieve pain, swelling and other symptoms of inflammation
- arthritis medicines including gold therapy
- potassium supplements or potassium-containing salt substitutes
- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene, amiloride); medicines which may increase potassium levels (e.g. heparin, trimethoprim/sulfamethoxazole)
- lithium, a medicine used to treat mood swings and some types of depression
- insulin or oral antidiabetic medicines. You should be closely monitored for low blood glucose levels, especially during the first month of treatment with Enalapril Sandoz.
- mammalian target of rapamycin inhibitors (e.g. temsirolimus, sirolimus, everolimus).

These medicines may be affected by Enalapril 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.

How to take Enalapril Sandoz

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

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 Enalapril Sandoz only when prescribed by your doctor.

For high blood pressure:

For most patients, the usual starting dose is 5mg 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 40mg each 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 up to 20mg each day. This dose may be taken once a day or divided into two doses per day.

How to take it

Take your Enalapril Sandoz 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 Enalapril Sandoz with a glass of water. It does not matter if you take Enalapril Sandoz before or after food.

If you need to break Enalapril Sandoz, place the tablet on a flat surface with the notch side facing up and press down on the scored side with the thumb.

How long to take it

Enalapril Sandoz helps control your high blood pressure and helps improve your heart failure, but does not cure it. Therefore this medicine must be taken every day.

Continue taking your medicine for as long as your doctor prescribes.

If you forget to take your dose

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 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 when 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 you or anyone else may have taken too much Enalapril Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are taking Enalapril Sandoz

Things you must do

Always follow your doctor's instructions carefully.

Have your blood pressure checked when your doctor says, to make sure Enalapril Sandoz is working.

If you feel any light-headedness or dizziness after you take your first dose of Enalapril Sandoz or if your dose is increased, tell your doctor immediately. This is especially important if you are

taking Enalapril Sandoz 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 may be 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, or plan on becoming pregnant while taking Enalapril Sandoz, tell your doctor immediately.

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

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

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

Your blood pressure may drop suddenly.

If you are about to have any blood tests, tell your doctor that you are taking Enalapril Sandoz. It may interfere with the results of some tests.

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

If you do not drink enough water while taking Enalapril Sandoz, 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 Enalapril Sandoz, tell your doctor.

This can also mean that you are losing too much water and salt, 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 to see how your kidneys are working.

Things you must not do

Do not stop taking Enalapril Sandoz without your doctor's permission.

Do not take Enalapril Sandoz to treat any other complaint unless your doctor tells you to.

Do not give this medication 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 Enalapril Sandoz affects you.

Enalapril Sandoz may cause dizziness or light-headedness in some people, especially after the first dose or if the dose is increased. Make sure you know how you react to Enalapril Sandoz 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 or at least cut down smoking.
- **Weight**
Your doctor may suggest losing some weight to 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 Enalapril 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 possible side effects. You may not experience any of them.

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 because your blood pressure is too low
- headache
- fatigue
- dry cough

- mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
- muscle cramps
- feelings of deep sadness and unworthiness (depression)

These are the usually mild side effects of Enalapril Sandoz, but may be serious.

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

- changes in the way your heart beats, for example, if you notice it beating faster
- fainting
- yellowing of the skin and eyes, also called jaundice
- itchy skin rash or other skin problems
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing less urine than is normal for you
- signs of dehydration such as nausea, vomiting, muscle cramps, headache, drowsiness and tiredness. If untreated, mental confusion and fits may develop. Your doctor may need to monitor your blood sodium levels.
- strange dreams or unusual dreams
- hallucinations (seeing or hearing things that are not there).

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare.

If any of the following happen, stop taking Enalapril Sandoz, and 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
- swelling of the hands, feet or ankles

- pinkish, itchy swelling on the skin, also called hives or nettle rash
- chest pain, angina
- wheeziness due to tightness in the chest
- collapse, numbness or weakness of arms or legs.

These are 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 that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After taking Enalapril Sandoz

Storage

Keep your medicine in the original packaging until you need to take it.

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

Keep your medicine in a cool dry place where the temperature stays below 25°C and where it is protected from light and moisture.

Do not store Enalapril Sandoz or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

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.

Product description

What Enalapril Sandoz looks like

Enalapril Sandoz comes in three types of tablets:

Enalapril Sandoz 5mg - oval, convex, white tablets, with one side scored and marked EN 5.

Enalapril Sandoz 10mg - oval, convex, red-brown tablets, with one side scored and marked EN 10.

Enalapril Sandoz 20mg - oval, convex, orange tablets, with one side scored and marked EN 20.

Available in blisters of 30 tablets.

Ingredients

Active Ingredient

Each Enalapril Sandoz 5mg tablet contains 5mg enalapril maleate

Each Enalapril Sandoz 10mg tablet contains 10mg enalapril maleate

Each Enalapril Sandoz 20mg tablet contains 20mg enalapril maleate

Inactive Ingredients

- sodium bicarbonate
- lactose
- maize starch
- purified talc
- magnesium stearate
- hydroxypropylcellulose (5mg tablets only)
- iron oxide red (10 and 20mg tablets only)
- iron oxide yellow (20mg tablets only).

This medicine does not contain 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

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Australian Register Numbers

Enalapril Sandoz 5mg tablets:
 AUSTR 121813

Enalapril Sandoz 10mg tablets:
 AUSTR 121814

Enalapril Sandoz 20mg tablets:
 AUSTR 121816