

ENALAPRIL/HCT SANDOZ®

20 mg/6 mg Tablets

enalapril maleate and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Enalapril/HCT Sandoz 20 mg/6 mg. 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 Enalapril/HCT Sandoz 20 mg/6 mg 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/HCT Sandoz 20 mg/6 mg is used for

Enalapril/HCT Sandoz 20 mg/6 mg lowers high blood pressure, which doctors call 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/HCT Sandoz 20 mg/6 mg helps to lower your blood pressure.

How Enalapril/HCT Sandoz 20 mg/6 mg works

Enalapril/HCT Sandoz 20 mg/6 mg contains two active ingredients. One of these is enalapril maleate. It belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors. It works by widening your blood vessels. This means that blood is able to pass through them more easily and the heart doesn't have to pump as hard to move blood around the body.

The other active ingredient is hydrochlorothiazide, which is a fluid tablet or diuretic. It helps reduce the amount of fluid in the body by making your kidneys pass more water and salt.

Both of these active ingredients help to lower high blood pressure.

Your doctor may have prescribed Enalapril/HCT Sandoz 20mg/6mg for another reason. Ask your doctor if you have any questions about why Enalapril/HCT Sandoz 20mg/6mg has been prescribed for you.

Enalapril/HCT Sandoz 20mg/6mg is not addictive.

Before you take Enalapril/HCT Sandoz 20 mg/6 mg

When you must not take it

Do not take this medicine if:

- you are allergic to Enalapril/HCT Sandoz 20mg/6mg, Enalapril Sandoz or other brands of enalapril maleate, or hydrochlorothiazide, or any of the inactive ingredients mentioned 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 breathing; fever; swelling of the face, lips, tongue or other parts of the body; skin rash, itching or hives on the skin; muscle pain or tenderness, or joint pain.
- you have an allergy to any sulfur medicines or sulfonamide antibiotics. One of the active ingredients in this medicine, hydrochlorothiazide, is a sulfur-containing medicine (a sulfonamide). Therefore, if you are allergic to sulfur medicines, such as some antibiotics or some tablets used to treat diabetes, you are likely to be allergic to Enalapril/HCT Sandoz 20 mg/6 mg. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfur medicines.
- 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.
If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to this medicine.
- you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason
- you have renal artery stenosis, a disease of the kidney
- you are not passing urine
- you have diabetes and are taking a medicine called aliskiren to reduce blood pressure
- you are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril). Do not take Enalapril/HCT Sandoz 20 mg/6 mg for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.
- you are pregnant or breastfeeding. Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.
- it is past its expiry date or the packaging appears to have been tampered with. If you take this medicine after the expiry date has passed, it may not work.
- you have or have had any medical conditions, especially the following:
 - kidney disease, or if you are undergoing dialysis
 - passing less urine than is normal
 - liver disease
 - heart problems
 - diabetes.
- you are following a very low salt diet
- you are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other drugs that may increase serum potassium (eg. Trimethoprim-containing products)
- you have an allergy to any other medicines, especially if they are in the same drug class as enalapril maleate or hydrochlorothiazide
- you have had an allergy to any other substances, including foods, preservatives or dyes
- you have recently suffered from excessive vomiting or diarrhoea
- you suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing)
- surgery and anaesthesia (even at the dentist office) are scheduled, as there may be a sudden fall in blood pressure associated with anaesthesia
- you are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril).
- you are taking a medicine containing vildagliptin
- you have had skin cancer or if you develop a new skin lesion during the treatment. Treatment with hydrochlorothiazide, particularly long-term use with high doses, may increase the risk of some types of skins and lip cancer (non-melanoma skin cancer). Discuss with your doctor how to protect your skin from sun exposure, and avoid artificial tanning.
You experience any fever, breathing faster than normal or severe shortness of breath or difficulty breathing, slightly blue fingertips and lips after taking Enalapril/HCT Sandoz 20mg/6mg, stop the medication and seek medical attention immediately

If you have not told your doctor about any of the above, tell them before you start taking Enalapril/HCT Sandoz 20mg/6mg tablets.

Taking other medicines

Tell your doctor 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/HCT Sandoz 20mg/6mg may interfere with each other. These include:

- other fluid tablets (diuretics)
 - other medicines used to treat high blood pressure
 - lithium, used to treat severe mood swings and some types of depression
 - potassium tablets or potassium-containing salt substitutes
- Before you start to take it**
- Tell your doctor if:**
- you plan on becoming pregnant or will be breastfeeding while you are using this medicine. It should not be used during pregnancy or while breastfeeding.

- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene, amiloride)
- other drugs that may increase serum potassium levels (e.g., trimethoprim-containing products)
- steroid medicines such as cortisone, prednisone
- insulin and tablets used to treat diabetes
- barbiturates, used to treat epilepsy, such as phenobarbitone
- strong pain killers such as codeine, morphine, dextropropoxyphene
- non-steroidal anti-inflammatory drugs (NSAIDs or COX-2 inhibitors) used to treat inflammation, pain, arthritis
- arthritis medicines including gold therapy
- insulin or oral antidiabetic medicines. You should be closely monitored for low blood glucose levels, especially during the first month of treatment with Enalapril/HCT Sandoz 20 mg/6 mg.
- mammalian target of rapamycin inhibitors (e.g. temsirolimus, sirolimus, everolimus) or a medicine containing a neprilysin inhibitor (e.g. sacubitril) or vildagliptin as coadministration with Enalapril/HCT Sandoz 20mg/ 6mg could increase the risk for an allergic reaction called angioedema
- cholestyramine and colestipol, used to treat high cholesterol
- medicines used to relax muscles before or during surgery
- medicines used in emergency situations, such as adrenaline (epinephrine)
- alcohol.

These medicines may be affected by Enalapril/HCT Sandoz 20mg/6mg, 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Enalapril/HCT Sandoz 20 mg/6 mg

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.

For most patients, the usual dose is one tablet a day.

When to take Enalapril/HCT Sandoz 20 mg/6 mg

Take Enalapril/HCT Sandoz 20 mg/6 mg at about the same time each day.

This is best in the morning, for example, at breakfast time. Taking it at the same time each day will have the best effect. It will also help you remember when to take the tablets.

How to take it

Swallow the tablet whole with a full glass of water.

How long to take it

Enalapril/HCT Sandoz 20 mg/6 mg helps control your high blood pressure but does not cure it. Therefore it must be taken every day. Continue taking this medicine for as long as your doctor prescribes.

If you forget to take it

If it is less than six hours until 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.

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 has taken too much Enalapril/HCT Sandoz 20 mg/6 mg. 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. You may also become very thirsty, confused, have a change in the amount of urine passed or have a fast heart beat.

While you are taking Enalapril/HCT Sandoz 20 mg/6 mg

Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor immediately if you become pregnant while taking this medicine.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Enalapril/HCT Sandoz 20 mg/6 mg.

Have your blood pressure checked when your doctor says, to make sure this medicine is working.

If you feel any light-headedness or dizziness after you take your first dose of Enalapril/HCT Sandoz 20 mg/6 mg or if your dose is increased, tell your doctor immediately.

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

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.

Tell your doctor immediately in case of acute onset of decreased visual acuity or ocular pain.

These could be symptoms of fluid accumulation in the vascular layer of the eye

(choroidal effusion) or an increase of pressure in your eye and can happen within hours to weeks of taking Enalapril/HCT Sandoz 20 mg/6 mg. This can lead to permanent vision loss, if not treated.

If you have excessive vomiting and/or diarrhoea while taking this medicine, or you have any of the following symptoms, tell your doctor:

- dry mouth, thirst
- weakness, tiredness, drowsiness
- muscle pains or cramps
- fast heart beat
- passing less urine than normal.

You may be dehydrated because you are losing too much water. This may also drop your blood pressure too much.

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

If you do not drink enough water while taking it, 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 plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking Enalapril/HCT Sandoz 20 mg/6 mg.

Your blood pressure may drop suddenly.

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 this medicine without your doctor's permission.

Do not use it to treat any other complaints unless your doctor says so.

Do not give this medication to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

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

It 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/HCT Sandoz 20 mg/6 mg 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

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, fruits, 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 program 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 taking Enalapril/HCT Sandoz 20 mg/6 mg.

Enalapril/ HCT Sandoz 20 mg/ 6mg helps most people with high blood pressure, but it may have unwanted side effects in a few people. 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.

Hydrochlorothiazide, a component of this medicine, can cause:

- increases sensitivity of the skin to the sun and may increase the risk of some types of skin and lip cancer (non-melanoma skin cancer).
- Breathing faster than normal or severe shortness of breath or difficulty breathing. Slightly blue fingertips and lips.
- a decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma.

Do not be alarmed by this list 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:

- headache
- dry cough
- light-headedness or dizziness because blood pressure is too low
- tiredness or weakness
- feeling sick (nausea), vomiting, loss of appetite
- diarrhoea, constipation, stomach upset, pains or cramps
- restlessness
- muscle cramps
- transient blurred vision or yellow vision.

These are usually mild side effects of Enalapril/HCT Sandoz 20 mg/6 mg, 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

- severe dizziness, spinning sensation
- skin rash, itchiness or other skin problems
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- signs of anaemia such as tiredness, headache, being short of breath when exercising, looking pale
- passing less urine than is normal for you
- yellowing of the skin and/or eyes, also called jaundice
- numbness or tingling in the hands or feet
- 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.

These may be serious side effects of Enalapril/HCT Sandoz 20 mg/6 mg. You may need urgent medical attention.

Serious side effects are rare.

If any of the following happen, stop taking this medicine and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, throat or tongue 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 chest tightness, shortness of breath
- collapse, numbness or weakness of arms and legs.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

All of 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.

After taking Enalapril/HCT Sandoz 20 mg/6 mg

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. Protect from light.

Do not store Enalapril/HCT Sandoz 20 mg/6 mg tablets 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.

Product Description

What it looks like

Enalapril/HCT Sandoz 20 mg/6 mg tablets are white, oval, biconvex tablets with a snap tab on one side, scored and marked "EN20" on the other side. This medicine is available in blister packs of 30 tablets.

Ingredients

Active ingredients:

Each Enalapril/HCT Sandoz 20 mg/6 mg tablet contains 20 mg enalapril maleate and 6 mg hydrochlorothiazide.

Inactive Ingredients:

- lactose monohydrate
- magnesium stearate
- maize starch
- sodium bicarbonate
- purified talc.

Supplier

Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Australia
Tel 1800 726 369

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