

LEAFLET: INFORMATION FOR THE USER

Enalapril maleate Sandoz 5 mg, tablets
Enalapril maleate Sandoz 10 mg, tablets
Enalapril maleate Sandoz 20 mg, tablets
enalapril maleate

Read the entire leaflet carefully before you start taking this medicine because it contains important information for you.

Keep this leaflet. You may need to read it again.

Do you have any questions? Please contact your doctor or pharmacist.

Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.

Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor or pharmacist.

Contents of this leaflet:

1. What is Enalapril maleate Sandoz and what is it used for?
2. When should you not take this medicine or be extra careful?
3. How should you take this medicine?
4. Possible side effects
5. How should you store this medicine?
6. Contents of the pack and other information

1. WHAT IS ENALAPRIL MALEATE SANDOZ AND WHAT IS IT USED FOR?

Enalaprilmaleate Sandoz contains an active substance called enalapril maleate. This substance belongs to a group of medicines called ACE (angiotensin-converting enzyme) inhibitors.

Enalaprilmaleate Sandoz is used:

for the treatment of high blood pressure (hypertension)

for the treatment of reduced heart function (heart failure). It can reduce the need to go to the hospital and can help some patients live longer

to prevent the symptoms of heart failure. The symptoms include: shortness of breath, fatigue after light physical activity such as walking, or swollen ankles and feet.

This medicine widens your blood vessels. This lowers your blood pressure. The effect of the medicine usually begins within an hour and lasts at least 24 hours. Some patients need several weeks of treatment before the effect on blood pressure is optimal.

2. WHEN SHOULD YOU NOT TAKE THIS MEDICINE OR BE EXTRA CAUTIOUS?

When should you not use this medicine?

You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

You have had an allergic reaction in the past to a similar medicine as enalapril maleate (ACE inhibitor).

If you have ever had swelling of the face, lips, mouth, tongue, or throat with difficulty swallowing or breathing (angioedema) of unknown or hereditary cause.

You have diabetes or impaired kidney function and are being treated with a blood pressure-lowering medicine that contains aliskiren.

If you are more than 3 months pregnant. (It is also better not to use this medicine at the beginning of pregnancy – see also 'Pregnancy'.)

If you are using or have used sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, because the risk of angioedema (a rapid swelling under the skin, in a place such as the throat) is increased.

Do not use this medicine if any of the above warnings apply to you.

If you are unsure, contact your doctor or pharmacist.

When should you be extra cautious with this medicine?

Contact your doctor or pharmacist before using this medicine:

If you are using any of the following medicines, the risk of angioedema may be increased:

- Racecadotril, a medication for the treatment of diarrhea;
- Medications used to prevent rejection of an organ transplant and in the treatment of cancer (for example, temsirolimus, sirolimus, everolimus);
- Vildagliptin, a medication for the treatment of diabetes.

if you have a condition involving the blood vessels in your brain

if the composition of your blood is not right, for example, few or no white blood cells (neutropenia/agranulocytosis), few platelets (thrombocytopenia), or fewer red blood cells (anemia)

if you have liver problems

if you have kidney problems (including kidney transplantation). This can increase the concentration of potassium in your blood, which can be serious. Your doctor may need to adjust the dosage of this medicine or check the potassium in your blood

if you are on dialysis

if you have recently experienced excessive vomiting or diarrhea

if you are on a low-salt diet, use potassium supplements, potassium-sparing agents, or salt substitutes containing potassium

if you are over 70 years old

if you have diabetes. You should closely monitor for low blood sugar, especially during the first month of treatment. The concentration of potassium in your blood may also be higher

if you have ever had an allergic reaction accompanied by swelling of the face, lips, tongue, or throat with difficulty swallowing or breathing. Be aware that black patients have a higher risk of these reactions to ACE inhibitors

if you have low blood pressure (you notice this by a tendency to faint or dizziness, especially when standing)

if you have collagen vascular disease (for example, lupus erythematosus, rheumatoid arthritis, or scleroderma), are receiving therapy that suppresses your immune system, use the drugs allopurinol or procainamide, or a combination thereof

if you are taking any of the following medications for the treatment of high blood pressure:

- an angiotensin II receptor antagonist (ARBs) (also known as sartans – for example, valsartan, telmisartan, irbesartan), especially if you have diabetes-related kidney problems
- aliskiren

Your doctor may regularly check your kidney function, blood pressure, and the number of electrolytes (e.g., potassium) in your blood.

See also the information in the section “When should you not use this medicine?”.

Tell your doctor if you think you are pregnant or if you want to become pregnant. The use of this medicine is not recommended during the early stages of pregnancy. The medicine should not be used if you are more than 3 months pregnant, as it may cause serious adverse effects for the baby if used during this period (see also ‘Pregnancy’).

You should be aware that this medicine lowers blood pressure less in black patients than in non-black patients.

If you are not sure whether any of the above warnings apply to you, consult your doctor or pharmacist before using this medicine.

If you are about to undergo a procedure

If you are about to undergo any of the following procedures, tell your doctor that you are using this medicine:

- an operation or before you are anesthetized (even at the dentist)
 - a treatment to remove cholesterol from your blood called LDL apheresis
 - a treatment to make you less sensitive to the effect of an allergy to a bee or wasp sting
- If any of the above warnings apply to you, consult your doctor or dentist before the procedure

Are you using any other medicines?

Are you using any other medicines besides Enalaprilmaleaat Sandoz or have you recently done so, or is there a possibility that you will use other medicines in the near future? If so, tell your doctor or pharmacist.

This also applies to medicines that you can obtain without a prescription and for herbal preparations. This is because Enalaprilmaleaat Sandoz can affect the action of some medicines. Also, some medicines can affect the action of Enalaprilmaleaat Sandoz. Your doctor may adjust your dose and/or take other precautions.

Especially if you are using the following medicines, it is important to inform your doctor or pharmacist:

- an angiotensin II receptor antagonist (ARB) or aliskiren (see also the information in the sections ‘When should you not use this medicine?’ and ‘When should you be extra careful with this medicine?’)
- other blood pressure-lowering medicines, such as beta-blockers or diuretics
- Potassium supplements (including salt substitutes), potassium-sparing diuretics, and other medicines that can increase the amount of potassium in your blood (for example, trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, a medicine

that suppresses the immune system used to prevent rejection of an organ transplant; and heparin, a medicine used to thin the blood to prevent blood clots from forming)

- medicines for diabetes (including medicines you take orally and insulin)
- lithium (a medicine for certain forms of depression)
- medicines for depression (tricyclic antidepressants)
- medicines for mental problems (antipsychotics)
- certain cough and cold medicines and weight-reducing medicines that contain a so-called 'sympathomimetic'
- certain painkillers or medicines for arthritis, including gold therapy
- Medicines that are usually used to prevent rejection of transplanted organs (sirolimus, everolimus, and other medicines belonging to the class of mTOR inhibitors). See the section "When should you be extra careful with this medicine?"
- non-steroidal anti-inflammatory drugs, including COX-2 inhibitors (medicines for inflammation that can also relieve pain)
- aspirin (acetylsalicylic acid)
- medicines to dissolve blood clots (thrombolytics)
- alcohol

Consult your doctor or pharmacist before taking this medicine if you are unsure whether the above applies to you.

What should you pay attention to with food and drink?

This medicine can be taken with or without food. Most patients take this medicine with water.

Pregnancy and breastfeeding

Pregnancy

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine. Usually, your doctor will advise you to stop using this medicine before you become pregnant or as soon as you know you are pregnant and will prescribe another medicine instead. This medicine is not recommended for use during the early stages of pregnancy. The medicine should not be used if you are more than 3 months pregnant, as it can have serious adverse effects on the baby if used during this period.

Breastfeeding

Tell your doctor if you are breastfeeding or planning to start. Breastfeeding newborns (the first weeks after birth), and especially premature babies, is not recommended if you are using this medicine. If the child is older, your doctor should advise you on the benefits and risks of using this medicine during breastfeeding compared to other treatments.

Driving and using machines

You may feel dizzy or drowsy when using this medicine. If this happens, do not drive, use tools or machines.

Enalapril maleate Sandoz contains lactose.

If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine.

This medicine contains small amounts of ethanol (alcohol), less than 100 mg per tablet.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, meaning it is essentially 'sodium-free'.

3. HOW TO TAKE THIS MEDICINE?

Always take this medicine exactly as your doctor or pharmacist has told you. Unsure about the correct use? Then contact your doctor or pharmacist.

- It is very important to continue taking this medicine as long as your doctor prescribes it.
- Do not take more tablets than prescribed.

High blood pressure

- The recommended starting dose is 5 to 20 mg once daily.
- Some patients may require a lower starting dose.
- The recommended maintenance dose is 20 mg once daily.
- The maximum dose is 40 mg once daily.

Heart failure

- The recommended starting dose is 2.5 mg once daily.
- Your doctor will gradually increase this dose until the right dose for you is reached.
- The recommended maintenance dose is 20 mg per day taken as one or two doses.
- The maximum dose is 40 mg per day, divided into two doses.

Patients with kidney problems

The dosage of your medication depends on how well your kidneys work:

- moderate kidney problems – 5 to 10 mg per day.
- severe kidney problems – 2.5 mg per day.
- if you are on dialysis – 2.5 mg per day. On days you are not on dialysis, your dosage may be adjusted depending on your blood pressure level.

Use in the elderly

Depending on how well your kidneys work, your doctor will determine your dosage.

Use in children and adolescents up to 18 years

Experience with the use of this medicine in children with high blood pressure is limited. If the child can swallow tablets, the dosage will be determined based on the child's weight and blood pressure. The recommended starting dose is:

- between 20kg and 50 kg – 2.5 mg per day
- more than 50 kg – 5 mg per day.

The dose may change according to the child's needs:

- maximum 20 mg per day for children who weigh between 20 kg and 50 kg
- maximum 40 mg per day for children who weigh more than 50 kg.

This medicine is not recommended for newborns (first few weeks after birth) and for children with kidney problems.

The tablets can be divided into equal doses.

Instructions for removing the tablet from the blister pack

1^e Step: Use your fingernail to make a small notch in the blister foil from the printed side until it tears.

2^e Step: To easily remove the tablet from the blister, we recommend pressing on the side of the blister pack.

Have you taken too much of this medicine?

If you have taken too much Enalapril Maleate Sandoz, contact your doctor or pharmacist immediately. Take the medicine packaging with you. The following symptoms may occur: you may feel lightheaded or dizzy. This is due to a sudden or excessive drop in blood pressure.

Have you forgotten to take this medicine?

- If you forget to take a tablet, skip the missed dose.
- Take the next dose as usual.
- Do not take a double dose to make up for a forgotten dose.

If you stop taking this medicine

Do not stop taking Enalapril Maleate Sandoz without consulting your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everyone gets them.

Stop taking Enalapril Maleate Sandoz and contact your doctor immediately if you experience any of the following symptoms:

- swelling of the face, lips, tongue, or throat with possible difficulty breathing or swallowing
- swelling of hands, feet, or ankles
- red skin rash (hives).

You should be aware that Black patients have an increased risk of these types of reactions. Stop taking this medicine and consult your doctor immediately if you experience any of the above symptoms.

When you start taking this medicine, you may feel faint or dizzy. If this happens, it helps to lie down. This feeling is caused by the lowering of your blood pressure. If you continue taking the medicine, this should improve. Consult your doctor if you are concerned.

Other side effects include:

Very common (may affect more than 1 in 10 patients):

- dizziness, feeling weak or unwell
- blurred vision
- cough

Common (may affect up to 1 in 10 people):

- lightheadedness due to low blood pressure, arrhythmias, rapid heartbeat, pain in the heart area (angina pectoris) or chest pain
- headache, depression, fainting (syncope)
- altered taste
- shortness of breath
- diarrhea, abdominal pain
- fatigue
- rash, allergic reactions with swelling of the face, lips, tongue, and/or throat with difficulty swallowing or breathing
- high potassium levels in the blood (hyperkalemia), too much creatinine in the blood (both are usually detected by blood tests)

Sometimes (may affect up to 1 in 100 people):

- excessive blushing
- sudden drop in blood pressure
- rapid or irregular heartbeat (palpitations)
- heart attack (possibly due to extremely low blood pressure in high-risk patients, including those with impaired blood flow to the heart and/or brain)
- stroke (possibly due to extremely low blood pressure in high-risk patients)
- anemia (including aplastic and hemolytic anemia)
- confusion, insomnia or drowsiness, nervousness
- tingling or numbness of the skin
- dizziness
- ringing in the ears (tinnitus)
- nasal cold, sore throat or hoarseness
- asthma-related chest tightness
- intestinal contents cannot be moved forward (ileus), inflammation of the pancreas (pancreatitis)
- vomiting, indigestion, constipation, loss of appetite (anorexia)
- stomach irritation, dry mouth, stomach ulcer (gastric ulcer)
- muscle cramp
- kidney dysfunction, kidney failure
- increased sweating
- itching or hives (urticaria)
- hair loss
- feeling unwell (malaise), increased temperature (fever)
- impotence
- high protein levels in the urine (proteinuria) (measured during examination)
- low blood sugar or sodium levels, high blood urea levels (all measured in blood tests)

Rare (may affect up to 1 in 1,000 people):

Raynaud's phenomenon, your hands and feet may become very cold and white due to poor circulation
changes in blood values such as fewer white or red blood cells, lower hemoglobin levels, fewer platelets
deterioration of bone marrow function (bone marrow depression)
swollen glands in the neck, armpit, or groin
autoimmune diseases
strange dreams or sleep disorders
accumulation of fluid or other substances in the lungs (seen on an X-ray)
inflammation of the nasal mucosa (rhinitis)
pneumonia with difficulty breathing as a result
inflammation of the cheeks, gums, tongue, lips, throat
reduced amount of urine (oliguria)
skin rash with red irregular spots (erythema multiforme)
'Stevens-Johnson syndrome' and 'toxic epidermal necrolysis' (severe skin conditions with redness and peeling, blisters, or open sores), exfoliative dermatitis/erythroderma (severe skin rash with peeling or loss of skin), pemphigus (fluid-filled blisters on the skin)
Liver or gallbladder problems such as impaired liver function, liver inflammation, jaundice (yellowing of the skin or eyes), high concentrations of liver enzymes or bilirubin (measured in blood tests)
Breast development in men (gynecomastia)

Very rare (may affect up to 1 in 10,000 people):
swelling in the intestines (intestinal angioedema).

Unknown (cannot be determined from the available data)
fluid retention due to overproduction of antidiuretic hormone with resulting weakness, fatigue, or confusion
a symptom complex has been reported with some or all of the following symptoms: fever, inflammation of the blood vessels (serositis, vasculitis), muscle pain (myalgia/myositis), joint pain (arthralgia/arthritis). Rash, photosensitivity, or other skin conditions may also occur.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. HOW TO STORE THIS MEDICINE

Keep out of the sight and reach of children.

Store below 25°C.

Do not use this medicine after the expiry date. This can be found on the packaging after "Exp.:". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What substances are in this medicine?

The active substance in this medicine is enalapril maleate. Per tablet respectively 5, 10, or 20 mg enalapril maleate

The other substances in this medicine are sodium bicarbonate, lactose monohydrate, corn starch, talc, and magnesium stearate.

The 5 mg tablets also contain hydroxypropyl cellulose.

The 10 mg tablets contain the coloring agent iron oxide red (E172).

The 20 mg tablets contain the coloring agents iron oxide red and yellow (E172).

What does Enalapril Maleate Sandoz look like and how much is in a package?

Enalapril Maleate Sandoz 5 mg is a white oval, biconvex, with a score line and the imprint "EN 5" on one side.

Enalapril Maleate Sandoz 10 mg is a reddish-brown oval, biconvex, with a score line and the imprint "EN 10" on one side.

Enalapril Maleate Sandoz 20 mg is an orange oval, biconvex, with a score line and the imprint "EN 20" on one side.

The tablets are packed per 30 or 90 in blister strips in a cardboard box. Not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Netherlands

Manufacturer

Salutas Pharma GmbH

Otto-von-Guericke Allee 1

39179 Barleben

Germany

Sandoz B.V.

10/10

Enalaprilmaleaat Sandoz® 5/10/20 mg, tabletten

1313-v17

RVG 23648-23649-23650

1.3.1.3 Bijstufiter

November 2025

Lek Pharmaceuticals d.d.

Trimlini 2D

9220 Lendava

Slovenia

Registered under:

Enalapril maleate Sandoz is registered under RVG 23648 (5 mg), RVG 23649 (10 mg) and RVG 23650 (20 mg).

This leaflet was last approved in October 2025.