

Please read this leaflet carefully before you start to receive your medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What RENITEC 5 mg tablets is and what it is used for
2. Before you take RENITEC 5 mg tablets
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RENITEC[®] 5 mg tablets
Enalapril

Each tablet contains as active substance 5 mg of enalapril (maleate).

The excipients are sodium bicarbonate, lactose, corn starch and magnesium stearate.

License holder:

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1. WHAT RENITEC 5 mg TABLETS IS AND WHAT IT IS USED FOR

RENITEC is available in tablets. Each package contains 10 and 60 tablets. The tablets are white, biconvex, barrel shaped, scored and marked "RENITEC" on one side.

RENITEC belongs to the group of drugs called angiotensin converting enzyme inhibitors, (ACE inhibitors).

RENITEC is indicated to:

- Treat hypertension (high blood pressure).
- Treat symptomatic heart failure.
- Prevent symptomatic heart failure.

2. BEFORE YOU TAKE RENITEC 5 mg TABLETS

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Do not take RENITEC:

- If you are allergic to enalapril or to any of the ingredients of the medicinal product.
- If you have previously been treated with a medication in the same group of drugs as RENITEC (ACE Inhibitors) and have had allergic reactions with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing.
- If you have been diagnosed with hereditary or idiopathic angioedema (it is the development of big wheals in the surface of the skin, especially around the eyes and lips, which can also affect the hands, feet and throat, and which may also involve swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing).
- If you are pregnant, or think you may be pregnant.

Take special care with RENITEC:

- If you have a heart condition.
- If you have blood disorders.
- If you have diabetes.
- If you have liver problems.
- If you have kidney problems (including kidney transplantation).
- If you are undergoing dialysis.
- If you are being treated with diuretics (drugs to increase the urine elimination).
- If you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents or potassium-containing salt substitutes, or if you have recently suffered from excessive vomiting or diarrhea.
- If during the treatment an allergic reaction with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing occurs.
- If you are about to have a treatment called LDL apheresis, or are about to have desensitization treatment to reduce the effect of an allergy to bee or wasp stings.
- If you suffer from low blood pressure (you may notice this as faintness or dizziness, especially in the initial doses and when standing. In these cases, it could help you to lie down).

In all these cases, inform your doctor because you may need a dose adjustment or discontinue the treatment with RENITEC.

Before surgery and anesthesia (even at the dentist's office), tell the doctor or dentist that you are taking RENITEC as there may be a sudden fall in blood pressure associated with anesthesia.

Taking RENITEC with food and drink:

Food does not affect the absorption of RENITEC.

Alcohol enhances the hypotensive (reduction of blood pressure) effect of enalapril, therefore, tell your doctor if you are taking drinks which contain alcohol while on treatment with this medicine.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking, or have recently taken any other medicine - even those not prescribed.

Certain medicines can interact with RENITEC; in these cases, dosage adjustment or discontinue the treatment with any of the medicines can be necessary.

It is especially important that you inform your doctor if you are taking some of the following medicines:

- Antihypertensives medicines (to reduce high blood pressure)

- Diuretics (medicines to increase the urine elimination)
- Medicines containing potassium (including dietary salt substitutes)
- Lithium (medicines used to treat a certain kind of depression)
- Tricyclic antidepressants
- Antipsychotic agents
- Anesthetics
- Antidiabetic agents
- Non-steroidal anti-inflammatory drugs (NSAIDs) (medicines to treat pain or certain inflammations, i. e, acetylsalicylic acid)
- Sympathomimetic agents

Pregnancy:

Ask your doctor or pharmacist for advice before taking any medicine.

RENITEC should not be used in pregnant women. If you are pregnant or intend to become pregnant, you must tell your doctor before starting therapy with RENITEC so that another treatment may be considered.

Breast-feeding:

Ask your doctor or pharmacist for advice before taking any medicine.

RENITEC is secreted in human milk in very small amounts, therefore, while on treatment with this medicine breast-feeding should be interrupted. **Driving and using machines:**

Individual responses to medication may vary.

Since RENITEC can cause dizziness or weariness, try not to perform tasks that require special attention (driving an automobile or operating machinery) until you know how you tolerate the medication.

Important information about some of the ingredients of RENITEC:

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE RENITEC 5 mg TABLETS

Follow these instructions unless your doctor gave you different advice.

Remember to take your medicine.

Your doctor will tell you the duration of your treatment with RENITEC. Do not interrupt the treatment before.

RENITEC may be taken with or between meals together with a drink of water.

Your doctor will decide on the appropriate dose of RENITEC you should take, depending on your condition and whether you are taking other medicines.

High Blood Pressure

For most patients, the usual recommended starting dose is 5 to 20 mg taken once a day. Some patients may need a lower starting dose.

The usual long term dose is 20 mg taken once a day.

Heart Failure

The usual recommended starting dose is 2.5 mg taken once a day. Your doctor will increase this amount step by step until the dose that is right for you have been achieved. The usual long term dose is 20 mg per day taken in one or two doses.

At the beginning of treatment, due to the possibility of lightheadedness or dizziness carry precautions to extremes.

Let your doctor know immediately if you feel these symptoms.

If you have the impression that the effect of RENITEC 5 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more RENITEC than you should:

If you take more RENITEC than you should, contact your doctor or pharmacist immediately.

In case of an overdose, the most likely symptom is a feeling of lightheadedness or dizziness due to a sudden or excessive drop in blood pressure.

In case of overdosage or accidental ingestion, consult the Information Service of Toxicology. Telephone: 91-562 04 20.

If you forget to take RENITEC:

You should keep on taking RENITEC as prescribed. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, RENITEC can have side effects.

Blood and lymphatic system disorders:

Uncommon: anaemia (including aplastic and hemolytic anemia).

Rare: blood disorders, such as abnormally low number of neutrophils, low levels of haemoglobin, reduction or complete absence of granulocytes, deficiency of all cell elements in the blood, bone marrow depression, disease of the lymph nodes or abnormal immune response.

Metabolism and nutrition disorders:

Uncommon: low blood sugar levels.

Nervous system and mental disorders:

Common: headache, depression.

Uncommon: confusion, sleepy or unable to sleep, nervousness, tingling sensations or numbness, vertigo.

Rare: abnormal dreams, sleep disorders.

Eye disorders:

Very common: blurred vision.

Heart and blood vessel disorders:

Very common: dizziness.

Common: fall in blood pressure (including orthostatic hypotension), fainting, heart attack or stroke, chest pain, heart rhythm disturbances, angina, fast heartbeat.

Uncommon: rapid forceful heartbeat.

Rare: small arteries, usually in the fingers and toes, go into spasm causing the skin to become pale or patchy red to blue colour (Raynaud's phenomenon).

Respiratory disorders:

Very common: cough.

Common: difficulty breathing.

Uncommon: runny nose, sore throat and hoarseness, asthma.

Rare: fluid on the lung, inflammation of the nasal mucus membrane, allergic inflammation of the lungs.

Gastro-intestinal disorders:

Very common: nausea.

Common: diarrhoea, abdominal pain, changes in taste.

Uncommon: obstruction of the gut, inflammation of the pancreas, vomiting, indigestion, constipation, anorexia, gastric irritations, dry mouth, peptic ulcer.

Rare: inflammation and ulceration of the mouth, inflammation of the tongue.

Very rare: intestinal angioedema.

Liver disorders:

Rare: liver failure, inflammation of the liver, reduction or stoppage of bile flow from the bile duct in the liver (cholestasis including jaundice).

Skin and subcutaneous tissue disorders:

Common: rash, hypersensitivity or allergic reaction causing swelling of the face, extremities, lips, tongue, glottis and larynx.

Uncommon: perspiration, itching, nettle-rash or hives, hair loss.

Rare: severe skin reaction, including excessive redness of the skin, blisters, skin peeling off in sheets.

A symptom complex has been reported which may include some or all of the following: fever, inflammation of the blood vessels, pain and inflammation of muscles and joints, blood disorders affecting the components of the blood and usually detected by a blood test, rash, hypersensitivity to sunlight and other effects on the skin.

Effects on the kidney and urinary output:

Uncommon: reduced kidney function or kidney failure, presence of protein in the urine.

Rare: reduction in the amount of urine produced per day.

Reproductive and breast disorders:

Uncommon: impotence.

Rare: enlargement of breasts in men.

General disorders:

Very common: weakness.

Common: tiredness.

Uncommon: muscle cramps, flushing, ringing in the ears, feeling unwell, fever.

Laboratory tests:

Common: high levels of potassium in the blood, increases of creatinine in the blood.

Uncommon: increases in urea in the blood, decreased levels of sodium in the blood.

Rare: elevated liver enzymes, raised levels of bilirubin in the blood.

Stop taking RENITEC and contact your doctor immediately in any of the following cases:

- If you develop swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing,
- If you experience swelling of the hands, feet or ankles,
- If you develop hives (itching and redness in some zones of the body).

You must take into account that black patients are more sensitive to these types of adverse reactions.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING RENITEC 5 mg TABLETS

Keep RENITEC out of the reach and sight of children.

Do not store above 30°C.

Expiration:

Do not use RENITEC after the expiry date on the carton.

This leaflet was approved on January 2005.