

RENITEC®

Enalapril Maleate (5mg, 10mg, 20mg)

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Please read this leaflet carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information in the previous leaflet may have changed.

Remember that your doctor has prescribed this medicine only for you. Never give it to anyone else.

What *RENITEC* is used for

RENITEC is a tablet.

RENITEC is a medication that belongs to the group of medicine called angiotensin converting enzyme inhibitors, (ACE inhibitors).

Your doctor has prescribed *RENITEC* to treat your hypertension (high blood pressure) or heart failure (weakening of heart function). *RENITEC* is also used for the prevention of symptomatic heart failure.

In many patients with heart failure who have symptoms, *RENITEC* slows the worsening of heart failure, reduces the need to go to the hospital as a result of heart failure, and helps some of these patients to live longer.

In many patients with early stage heart failure prior to the development of symptoms, *RENITEC* helps to prevent the weakening of heart function and to slow the development of symptoms (for instance, shortness of breath, tiredness after light physical activity such as walking, or swelling of the ankles and feet). These patients may be less likely to have hospital stays as a result of heart failure.

By taking *RENITEC*, some heart failure patients may lessen their risk of heart attack.

How *RENITEC* works

RENITEC works by widening your blood vessels to make it easier for the heart to pump blood to all parts of your body. This helps to reduce high blood pressure. In many patients with heart failure, *RENITEC* will help the heart to function better.

Information for Patients with High Blood Pressure

What is blood pressure?

The pressure caused by your heart pumping blood to all parts of your body is called blood pressure. Without blood pressure there would be no circulation of blood in your body. Normal blood pressure is part of good health. Your blood pressure changes during the day depending on activity, stress and excitement.

Your blood pressure reading is made up of two numbers, for instance 120/80. The top number measures the force while your heart pumps. The bottom number measures the force at rest, between heartbeats.

What is high blood pressure (or hypertension)?

You have high blood pressure or hypertension if your blood pressure stays high even when you are calm and relaxed. High blood pressure develops when the blood vessels tighten, making it harder for blood to pass.

How do I know if I have high blood pressure?

There are usually no symptoms of high blood pressure. The only way of knowing that you have hypertension is to know your blood pressure. For that reason, you should have your blood pressure checked on a regular basis.

Why should high blood pressure be treated?

High blood pressure, if left untreated, can damage vital organs like the heart and the kidneys. You may feel fine and have no symptoms, but eventually hypertension can cause strokes, heart attacks, heart failure, kidney failure or blindness. High blood pressure can be treated and controlled by taking medicines such as *RENITEC*.

Your doctor can tell you what your individual target blood pressure should be. Keep this number in mind and follow your doctor's advice on how to reach this target.

Information for Patients with Heart Failure

What is 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 a heart attack. Some patients experience heart failure after heart attacks. However, there are also other causes of heart failure.

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Patients in the early stages of heart failure may have no symptoms at all. As heart failure progresses, patients may feel shortness of breath or may get tired easily after light physical activity such as walking. Fluid may collect in different parts of the body, often first noticed around the ankles and feet. In severe heart failure, patients may have symptoms even at rest.

Why should heart failure be treated?

All of the symptoms of heart failure can limit your daily activities. Your doctor may recommend several medications that can improve the signs and symptoms of heart failure (for instance, *RENITEC* and/or a water tablet). If you follow your doctor's advice, your ability to perform daily activities may improve. You may breathe more easily, feel less tired and have less swelling.

In patients with heart failure who have no symptoms, treatment with medications such as *RENITEC* may help to delay the progression of the disease and the onset of symptoms. In some heart failure patients who have symptoms, *RENITEC* has been shown to slow the worsening of heart failure and to help these patients live longer. In many patients, *RENITEC* has also been shown to reduce the risk of heart attack and to reduce the need to go to the hospital as a result of heart failure.

Before you take *RENITEC*

- **When you must not take it**
Do not take *RENITEC* if you -

- are allergic to any of its ingredients. (See **Product Description, Ingredients** section.)

- 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. You should not take *RENITEC* if you have had these types of reactions without a known cause, or if you have been diagnosed with hereditary or idiopathic angioedema.
- have diabetes and are taking a medicine called aliskiren to reduce blood pressure.
- are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril). Do not take *RENITEC* for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.

If you are not sure whether you should start taking *RENITEC*, contact your doctor.

Use in Pregnancy

- The use of *RENITEC* is not recommended in pregnant women.
- It is not known whether the use of *RENITEC* in the first three months of pregnancy only can also cause harmful effects. In a published study, it was reported that babies whose mothers had taken an ACE inhibitor medicine during the first three months of pregnancy had an increased risk of birth defects. The number of birth defects was small and the study has not been repeated
- Angiotensin-converting enzyme inhibitors (ACE inhibitors), including *RENITEC*, can cause injury and death to the developing baby when taken during the

second and third trimesters of pregnancy.

- 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.

Use in Breast-feeding

- *RENITEC* is secreted in human milk in very small amounts. If you are breast-feeding or intend to breast-feed, consult your doctor.

Use in Children

- *RENITEC* has been studied in children. For more information, talk to your doctor.

- Before you start to take it

Tell your doctor about any medical problems you have or have had, and about any allergies.

Tell your doctor if you have a heart condition, are undergoing dialysis or are being treated with diuretics (water tablets) or if you have recently suffered from excessive vomiting or diarrhea. Also tell your doctor if you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other drugs that may increase serum potassium (e.g., trimethoprim-containing products), have diabetes or any kidney problems, as these may lead to increased levels of potassium in the blood which can be serious. In these cases, your doctor may need to adjust the dosage of *RENITEC* or monitor your blood level of potassium. If you have diabetes and are taking oral antidiabetic medicines or insulin, you should closely monitor for low blood glucose levels, especially during the first month of treatment with *RENITEC*.

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Tell your doctor if you have ever had an allergic reaction with swelling of the face, lips, tongue, and/or throat with difficulty in swallowing or breathing.

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

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.

Tell your doctor if you are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril).

Tell your doctor if you are taking a medicine containing vildagliptin.

- Taking other medicines

Can I take *RENITEC* with other medicines?

In general, *RENITEC* can be taken with other medicine. However, it is important to tell your doctor about other medicine that you are taking, including those obtained without a prescription, as some medicine may affect each other's action. For prescribing the correct dose of *RENITEC*, it is especially important for your doctor to know whether you are taking other drugs to reduce blood pressure, diuretics (water tablets), medicine containing potassium (including dietary salt substitutes) or other drugs that may increase serum potassium (e.g., trimethoprim-containing products), medicine for diabetes (including oral antidiabetic medicines and insulin), lithium (a medicine used to treat a certain kind of depression) or certain pain and arthritis medicines including gold therapy. Talk to your doctor if you are taking an mTOR inhibitor (e.g., temsirolimus, sirolimus,

everolimus) or a medicine containing a neprilysin inhibitor (e.g., sacubitril) or vildagliptin as coadministration with *RENITEC* could increase the risk for an allergic reaction called angioedema.

How to take *RENITEC*

- How much to take

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

High Blood Pressure

For most patients, the usual recommended starting dose is 10 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 has been achieved. The usual long term dose is 20 mg per day taken in one or two doses.

Be especially careful when you take your first dose or if your dose is increased. Let your doctor know immediately if you feel any lightheadedness or dizziness.

- When to take it

RENITEC may be taken with or between meals. Most people take *RENITEC* with a drink of water.

- How long to take it

Take *RENITEC* every day, exactly as your doctor has instructed. It is very important to continue taking *RENITEC* for as long as your doctor prescribes it. Do not take

more tablets than the prescribed dosage.

- If you forget to take it

You should take *RENITEC* as prescribed. However, if you miss a dose, do not take an extra dose. Just resume your usual schedule.

- If you take too much (overdose)

In case of an overdose, contact your doctor immediately so that medical attention may be given promptly. The most likely symptom would be a feeling of lightheadedness or dizziness due to a sudden or excessive drop in blood pressure.

While you are taking *RENITEC*

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking *RENITEC*.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not give *RENITEC* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Can I drive or operate machinery while using *RENITEC*?

Individual responses to medication may vary. Certain side effects that have been reported with *RENITEC* may affect some patients' ability to drive or operate machinery. (See **Side effects**)

Side effects

Any medicine may have unintended or undesirable effects,

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so-called side effects. *RENITEC* is generally well tolerated. The most frequent side effects are dizziness, headache, tiredness and weakness. Other side effects occurring less frequently are lightheadedness due to a drop in blood pressure, fainting, nausea, diarrhea, muscle cramps, rash and cough. Another side effect may be a feeling of dizziness or lightheadedness due to a drop in blood pressure when standing up quickly.

Other side effects may also occur rarely, and some of them may be serious. Ask your doctor or pharmacist for more information about side effects. Both have a more complete list of side effects.

Tell your doctor or pharmacist promptly about any of these or any other unusual symptoms.

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

You should be aware that black patients are at increased risk of these types of reactions to ACE inhibitors.

The initial dose may cause a greater fall in blood pressure than will occur following continued treatment. You may notice this as faintness or dizziness and it may help by lying down. If concerned, please consult your doctor.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side

Effects to Medicines (ConSERF) or Vaccines (AEFI)]

How can I learn more about *RENITEC* and high blood pressure or heart failure?

You may obtain further information from your doctor or pharmacist, who have more detailed information about *RENITEC* and your condition.

Storage and disposal of *RENITEC*

- Storage

Store *RENITEC* below 30°C (86°F).

Keep all medicines safely away from children.

- Disposal

Do not use this medicine after the month and year shown by the four numbers following EX (or EXP) on the container. The first two numbers indicate the month; the last two numbers indicate the year. You may obtain further information from your doctor or pharmacist, who has more detailed information.

Product description

- What it looks like

RENITEC 5MG TABLET:

White, barrel biconvex shaped tablet, one side scored, the other side engraved *RENITEC*.

RENITEC 10MG TABLET:

Rust red, barrel biconvex shaped tablet, one side scored, the other side engraved *RENITEC*.

RENITEC 20MG TABLET:

Peach, barrel biconvex shaped tablet, one side scored, the other side engraved *RENITEC*.

RENITEC is available in blister packs of 30's as *RENITEC* 5MG TABLET, *RENITEC* 10MG TABLET AND *RENITEC* 20MG TABLET.

- Ingredients

Active ingredient:

RENITEC contains either 5 mg, 10 mg or 20 mg of enalapril maleate as the active ingredient.

Inactive ingredients:

In addition, *RENITEC* contains the following inactive ingredients: sodium bicarbonate, lactose hydrous, corn starch, pregelatinized starch and magnesium stearate powder. *RENITEC* 10mg also contains red ferric oxide E172. *RENITEC* 20mg also contains red ferric oxide E172 and yellow ferric oxide E172.

- MAL numbers:

RENITEC 5MG TABLET:
MAL19940015ARZ

RENITEC 10MG TABLET:
MAL19940016ARZ

RENITEC 20MG TABLET:
MAL19940017ARZ

Manufacturer

Organon Pharma (UK) Limited
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Product Registration Holder

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Date of revision:

15/10/2025 (version 102020)

Serial Number

NPRA (R1/4) 22092021/171