PATIENT INFORMATION LEAFLET

INFORMATION FOR THE PATIENT ABOUT RENITEC ®

Read all of this leaflet carefully before you start taking RENITEC

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

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

RENITEC® 2,5 Tablet

(2,5 mg enalapril maleate)

RENITEC® 5 Tablet

(5 mg enalapril maleate)

RENITEC® 10 Tablet

(10 mg enalapril maleate)

RENITEC® 20 Tablet

(20 mg enalapril maleate)

WHAT RENITEC CONTAINS

RENITEC (enalapril maleate, MSD) is a tablet.

RENITEC tablets contain either 2,5 mg; 5 mg; 10 mg or 20 mg of enalapril maleate as the active ingredient.

In addition, RENITEC tablets contain the following inactive ingredients:

Sodium hydrogen carbonate, maize starch, pregelatinised starch, magnesium stearate, lactose monohydrate. In addition the 10 mg and 20 mg tablet contains iron oxide red (E172) and iron oxide yellow (E172) – 20 mg tablet only.

RENITEC tablets contain sugar.

WHAT RENITEC IS USED FOR

RENITEC is a medication that belongs to the group of medicines 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 patients with decreased heart function.

RENITEC works by widening your blood vessels to make it easier for the heart to pump blood to all parts of your body.

BEFORE YOU TAKE RENITEC

Do <u>not</u> take RENITEC if you:

- Are allergic to enalapril maleate or any of the other ingredients of RENITEC (see "**WHAT RENITEC CONTAINS"**)
- Have previously been treated with a medication in the same group of medicines as RENITEC (ACE Inhibitors) or angiotensin receptor blockers (ARBs) 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 angio-oedema

- If you have hypertrophic obstructive cardiomyopathy, a heart disorder in which the walls of the ventricles (lower heart chambers) thicken (hypertrophy) and become stiff and the thickened muscle blocks the flow of blood out of the heart.
- If you have severe kidney disease.
- If you have narrowing of the blood vessels to both kidneys or to a single kidney.
- If you have aortic stenosis, a narrowing of the aortic valve opening between the left ventricle (large pumping chamber of the heart) and the aorta (the main artery leading away from the heart).
- If you are taking diuretics (water pills) that cause your body to retain potassium such as spironolactone, triamterene and amiloride.
- Porphyria
- Lithium therapy: Using at the same time with RENITEC may lead to toxic blood concentrations of lithium
- Are pregnant and breastfeeding (see **Pregnancy and Breastfeeding)**

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

Take special care with RENITEC

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 diarrhoea. Also tell your doctor if you are on a salt-restricted diet, are taking potassium supplements, potassium-sparing agents or potassium-containing salt substitutes, 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.

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 anaesthesia (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 anaesthesia.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby while taking RENITEC, please consult your doctor, pharmacist or other health care professional for advice.

Use in pregnancy

- Pregnant women should not use RENITEC as it can cause birth defects

- 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 breastfeeding

RENITEC is secreted in human milk in very small amounts. If you are breastfeeding or intend to breastfeed, consult your doctor.

Driving and using machinery

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**).

Important information about some of the ingredients of RENITEC

Lactose

RENITEC contains lactose and therefore should not be used by patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption. RENITEC contains less than 200 mg of lactose per tablet.

Taking other medicines with RENITEC

If you are taking other medicines on a regular basis including complementary or traditional medicines, the use of RENITEC with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

In general, RENITEC can be taken with other medicines. However, it is important to tell your doctor about other medicines that you are taking, including those obtained without a prescription, as some medicines 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 medicines to reduce blood pressure, diuretics (water tablets), medicines containing potassium (including dietary salt substitutes), drugs 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.

HOW TO TAKE RENITEC

Do not share medicines prescribed for you with any other person.

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

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

Always take RENITEC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. 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 have the impression that the effect of RENITEC is too strong or too weak, talk to your doctor or pharmacist.

High Blood Pressure

For most patients, the usual recommended starting dose is 10 to 20 mg in tablet formulation taken once a day. Some patients may need a lower starting dose. The usual long term dose is a 20 mg tablet taken once a day.

Heart Failure

The usual recommended starting dose is a 2,5 mg tablet 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 a 20 mg tablet 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 light-headedness or dizziness.

If you take more RENITEC than you should:

In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

The most likely symptom would be a feeling of light-headedness or dizziness due to a sudden or excessive drop in blood pressure.

If you forget to take RENITEC

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

POSSIBLE SIDE EFFECTS

RENITEC can have side effects

Not all side effects reported for RENITEC are included in this leaflet. Should your general health worsen while taking RENITEC, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking RENITEC and tell your doctor immediately or go to the casualty department at your nearest hospital:

- 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RENITEC. You may need urgent medical attention or hospitalisation

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

The following are frequent side effects:

Headache, dizziness or light-headedness due to a drop in blood pressure when standing up quickly, fainting, cough, nausea, diarrhoea, rash, weakness, tiredness

The following are less frequent side effects:

Muscle cramps

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.

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

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 to lie down. If concerned, please consult your doctor.

STORING AND DISPOSING OF RENITEC

HOW LONG SHOULD I KEEP MY MEDICINE?

Do not use this medicine after the month and year following EXPIRES/VERVAL on the container.

HOW SHOULD I STORE RENITEC?

Store in a dry place at or below 25 °C. Protect from light.

Keep all medicines out of reach and sight of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

PRESENTATION OF RENITEC

RENITEC 2,5 tablets are available in blister packs of 14.

RENITEC 5, 10 and 20 tablets are available in blister packs of 28.

IDENTIFICATION OF RENITEC

RENITEC 2,5 is a white, oval-shaped tablet, one side flat, scored and engraved MSD 14, other side concave and scored.

RENITEC 5 is a white, barrel-shaped tablet, engraved "RENITEC" on one side, scored on reverse.

RENITEC 10 is a rust-red, barrel-shaped tablet, engraved "RENITEC" on one side, scored on reverse.

RENITEC 20 is a peach, barrel-shaped tablet, engraved "RENITEC" on one side, scored on reverse.

REGISTRATION NUMBERS

RENITEC 2,5: 28/7.1.3/0665

RENITEC 5: T/7.1.3/164

RENITEC 10: T/7.1.3/165

RENITEC 20: T/7.1.3/166

NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

MSD (Pty) Ltd

117 16th Road,

Halfway House

1685

South Africa

011 655 3000

DATE OF PUBLICATION

21 June 2013

WPPI-RNT-MF-082006