

RENITEC® PLUS 20/6

Enalapril maleate and hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RENITEC PLUS 20/6. 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 RENITEC PLUS 20/6 against the benefits they expect it will 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 RENITEC PLUS 20/6 is used for

RENITEC PLUS 20/6 lowers high blood pressure, which doctors call hypertension.

Everyone has blood pressure. This pressure helps get your 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. RENITEC PLUS 20/6 helps to lower your blood pressure.

RENITEC PLUS 20/6 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 RENITEC PLUS 20/6 for another reason. Ask your doctor if you have any questions about why RENITEC PLUS 20/6 has been prescribed for you.

RENITEC PLUS 20/6 is not addictive.

Before you take RENITEC PLUS 20/6

When you must not take it

Do not take RENITEC PLUS 20/6 if 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 RENITEC PLUS 20/6.

Do not take RENITEC PLUS 20/6 if you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.

Do not take RENITEC PLUS 20/6 if:

- **you have an allergy to RENITEC PLUS 20/6, RENITEC or other brands of enalapril maleate, or hydrochlorothiazide, or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include skin rash, itchiness, hives, fever, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness, or joint pain.

- **you have an allergy to any sulfur medicines or sulfonamide antibiotics**

One of the active ingredients in RENITEC PLUS 20 /6, 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 RENITEC PLUS 20/6. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfur medicines.

- **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 RENITEC PLUS 20/6 for at least 36 hours before or after you take sacubitril/valsartan, a medicine containing a neprilysin inhibitor.

Do not take RENITEC PLUS 20/6 if you are pregnant or breast-feeding

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

Do not take RENITEC PLUS 20/6 if:

- the packaging is torn or shows signs of tampering
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking RENITEC PLUS 20/6, talk to your doctor.

Do not give RENITEC PLUS 20/6 to a child.

The safety of RENITEC PLUS 20/6 in children has not been established.

Before you start to take it

Tell your doctor if:

1. you are or intend to become pregnant or intend to breast-feed

RENITEC PLUS 20/6 should not be used during pregnancy or while breast-feeding.

2. you have any medical conditions, especially the following:

- kidney disease, or if you are undergoing dialysis
- diabetes

- passing less urine than is normal
 - liver disease
 - heart problems
3. you have recently suffered from excessive vomiting or diarrhoea
 4. you are following a very low salt diet
 5. you are taking potassium supplements, potassium-sparing agents, potassium-containing salt substitutes or other drugs that may increase serum potassium (e.g., trimethoprim-containing products)
 6. you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes
 7. if you suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing)
 8. surgery and anaesthesia (even at the dentist office) are scheduled, as there may be a sudden fall in blood pressure associated with anaesthesia
 9. you are taking a medicine containing a neprilysin inhibitor (e.g., sacubitril)
 10. you are taking a medicine containing vildagliptin
 11. 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 skin and lip cancer (non-melanoma skin cancer). Discuss with your doctor how to protect your skin from sun exposure, and avoid artificial tanning

If you have not told your doctor about any of the above, tell them before you take any RENITEC PLUS 20/6.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and RENITEC PLUS 20/6 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
- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene, amiloride)
- other drugs that may increase serum potassium (e.g., trimethoprim-containing products)
- non-steroidal anti-inflammatory medicines (NSAIDs or COX-2 inhibitors) used to treat inflammation, pain, arthritis
- 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
- 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 RENITEC PLUS
- 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 RENITEC PLUS could

- increase the risk for an allergic reaction called angioedema
- colestyramine 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 RENITEC PLUS 20/6, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking RENITEC PLUS 20/6.

How to take RENITEC PLUS 20/6

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. Take RENITEC PLUS 20/6 only when prescribed by your doctor.

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

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Take your RENITEC PLUS 20/6 at about the same time each day. This is best in the morning, for example, at breakfast time.

Taking RENITEC PLUS 20/6 at the same time each day will have the

best effect. It will also help you remember when to take the tablets.

Swallow RENITEC PLUS 20/6 with a glass of water.

How long to take it

RENITEC PLUS 20/6 helps control your high blood pressure but does not cure it. Therefore RENITEC PLUS 20/6 must be taken every day. Continue taking RENITEC PLUS 20/6 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.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much RENITEC PLUS 20/6. Do this even if there are no signs of discomfort or poisoning.

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 using RENITEC PLUS 20/6

Things you must do

Have your blood pressure checked when your doctor says, to make sure RENITEC PLUS 20/6 is working.

If you feel any light-headedness or dizziness after you take your first dose of RENITEC PLUS 20/6 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 RENITEC PLUS. This can lead to permanent vision loss, if not treated.

If you become pregnant while taking RENITEC PLUS 20/6, tell your doctor immediately.

If you have excessive vomiting and/or diarrhoea while taking RENITEC PLUS 20/6, 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 RENITEC PLUS 20/6, especially if you sweat a lot.

If you do not drink enough water while taking RENITEC PLUS 20/6, 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 RENITEC PLUS 20/6.

Your blood pressure may drop suddenly.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking RENITEC PLUS 20/6.

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 give RENITEC PLUS 20/6 to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how RENITEC PLUS 20/6 affects you.

RENITEC PLUS 20/6 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 RENITEC PLUS 20/6 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, fruit, 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 you are taking RENITEC PLUS 20/6.

RENITEC PLUS 20/6 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 treatment if you get some of the side effects.

Hydrochlorothiazide, a component of this medicine, 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).

Hydrochlorothiazide, a component of this medicine, may cause 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.

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 RENITEC PLUS 20/6, 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, headaches, 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. You may need urgent medical attention.

Serious side effects are rare.

If any of the following happen, stop taking RENITEC PLUS 20/6 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 swellings on the skin, also called hives or nettlerash
- chest pain, angina
- wheeziness due to chest tightness, shortness of breath
- collapse, numbness or weakness of arms and legs

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

All of these side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using RENITEC PLUS 20/6

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack and store them in another container they will not keep well and they may become soft and pliable.

Keep RENITEC PLUS 20/6 in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

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 RENITEC PLUS 20/6 or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

RENITEC PLUS 20/6 comes as a blue, rounded triangle shaped tablet marked with MSD 734 on one side and a triangle on the other.

A box of RENITEC PLUS 20/6 contains 30 tablets.

Ingredients

Active ingredients:

Each tablet contains enalapril maleate 20 mg and hydrochlorothiazide 6 mg.

Inactive ingredients:

- sodium bicarbonate
- lactose monohydrate
- maize starch
- pregelatinised maize starch
- indigo carmine
- magnesium stearate

RENITEC PLUS 20/6 does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

RENITEC PLUS 20/6 is supplied in Australia by:

Organon Pharma Pty Ltd
Building A, 26 Talavera Road,
Macquarie Park NSW 2113,
AUSTRALIA

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