

RENITEC® PLUS 20/6

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using RENITEC PLUS 20/6?

RENITEC PLUS 20/6 contains the active ingredient enalapril maleate and hydrochlorothiazide. RENITEC PLUS 20/6 is used to lower high blood pressure, which doctors call hypertension.

For more information, see Section [1. Why am I using RENITEC PLUS 20/6?](#) in the full CMI.

2. What should I know before I use RENITEC PLUS 20/6?

Do not use if you have ever had an allergic reaction to RENITEC PLUS 20/6 or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use RENITEC PLUS 20/6?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with RENITEC PLUS 20/6 and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use RENITEC PLUS 20/6?

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

More instructions can be found in Section [4. How do I use RENITEC PLUS 20/6?](#) in the full CMI.

5. What should I know while using RENITEC PLUS 20/6?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using RENITEC PLUS 20/6.• Go to your doctor regularly for a check-up. Have your blood pressure checked when your doctor says, to make sure RENITEC PLUS 20/6 is working.• If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.• 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 have excessive vomiting and/or diarrhoea while taking RENITEC PLUS 20/6, tell your doctor.
Things you should not do	<ul style="list-style-type: none">• Do not give RENITEC PLUS 20/6 to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• RENITECPLUS 20/6 may cause dizziness or light-headedness in some people. 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.
Drinking alcohol	<ul style="list-style-type: none">• If you drink alcohol, dizziness or light-headedness may be worse.
Looking after your medicine	<ul style="list-style-type: none">• Keep it in a cool dry place where the temperature stays below 25°C.• Keep your tablets in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using RENITEC PLUS 20/6?](#) in the full CMI.

6. Are there any side effects?

Common side effects include headache, light-headedness or dizziness, tiredness or weakness, dry cough, nausea, vomiting, loss of appetite, diarrhoea, constipation, stomach upset, pain or cramps, muscle cramps, blurred or yellow vision. Serious side effects include fast or irregular heartbeat, chest pain, fainting, severe dizziness, yellowing of the skin or eyes, skin rash/itchiness/hives, worrying or frequent infections, signs of anaemia, signs of dehydration, numbness or tingling in the hands or feet, symptoms of an allergic reaction (i.e. swelling of the face or throat, hives, shortness of breath etc.), blue fingertips and lips, visual disturbances, swelling of the hands or feet, collapse, numbness or weakness of arms and legs.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

RENITEC[®] PLUS 20/6

Active ingredient(s): *enalapril maleate and hydrochlorothiazide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using RENITEC PLUS 20/6. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using RENITEC PLUS 20/6.**

Where to find information in this leaflet:

- [1. Why am I using RENITEC PLUS 20/6?](#)
- [2. What should I know before I use RENITEC PLUS 20/6?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use RENITEC PLUS 20/6?](#)
- [5. What should I know while using RENITEC PLUS 20/6?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using RENITEC PLUS 20/6?

RENITEC PLUS 20/6 contains the active ingredients **enalapril maleate and hydrochlorothiazide**. The active ingredient enalapril maleate 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.

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.

2. What should I know before I use RENITEC PLUS 20/6?

Warnings

Do not use RENITEC PLUS 20/6 if:

- you are allergic to enalapril 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
- 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
- Always check the ingredients to make sure you can use this medicine.
- you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.
- 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.
- you are pregnant or breast-feeding
- the packaging is torn or shows signs of tampering

Check with your doctor if you:

- have any other medical conditions especially the following:
 - kidney disease, or if you are undergoing dialysis
 - diabetes
 - passing less urine than is normal
 - liver disease
 - heart problems
- are or intend to become pregnant or intend to breast-feed
- have recently suffered from excessive vomiting or diarrhoea

- are following a very low salt 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)
- take any medicines for any other condition
- have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes
- suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing)
- are planning to have surgery and anaesthesia (even at the dentist office), as there may be a sudden fall in blood pressure associated with anaesthesia
- are taking a medicine containing neprilysin inhibitor (e.g., sacubitril)
- are taking a medicine containing vildagliptin
- 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.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take RENITEC PLUS 20/6 if you are pregnant or intend to become pregnant.

Do not take RENITEC PLUS 20/6 if you are breastfeeding or intend to breastfeed.

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

Use in children

- Do not give RENITEC PLUS 20/6 to a child.
- The safety of RENITEC PLUS 20/6 in children has not been established.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with RENITEC PLUS 20/6 and affect how it works.

Medicines that may increase the effect of RENITEC PLUS 20/6 or the risk of side effects include:

- other fluid tablets (diuretics)
- other medicines used to treat high blood pressure
- 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)
- steroid medicines such as cortisone, prednisone
- barbiturates, used to treat epilepsy, such as phenobarbitone
- strong pain killers such as codeine, morphine, dextropropoxyphene
- arthritis medicines including gold therapy
- 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
- alcohol

Medicines that may reduce the effect of RENITEC PLUS 20/6 include:

- non-steroidal anti-inflammatory medicines (NSAIDs or COX-2 inhibitors) used to treat inflammation, pain, arthritis
- colestyramine and colestipol, used to treat high cholesterol

Medicines that may be affected when taken with RENITEC PLUS 20/6 include:

- lithium, used to treat severe mood swings and some types of depression
- 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
- medicines used to relax muscles before or during surgery
- medicines used in emergency situations, such as adrenaline (epinephrine)

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect RENITEC PLUS 20/6.

4. How do I use RENITEC PLUS 20/6?

How much to take

- For most patients, the usual dose is one tablet a day.
- Follow the instructions provided and use RENITEC PLUS 20/6 until your doctor tells you to stop.
- 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.

When to take RENITEC PLUS 20/6

- 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.

How to take RENITEC PLUS 20/6

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

If you forget to use RENITEC PLUS 20/6

RENITEC PLUS 20/6 should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

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.

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

If you use too much RENITEC PLUS 20/6

If you think that you have used too much RENITEC PLUS 20/6, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should 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.

5. What should I know while using RENITEC PLUS 20/6?

Things you should do

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

Call your doctor straight away 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.
- experience any fever, breathing faster than normal or severe shortness of breath or difficulty breathing, slightly blue fingertips and lips after taking RENITEC PLUS. Stop the medication and seek medical attention immediately.
- experience 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 20/6. This can lead to permanent vision loss, if not treated.
- have excessive vomiting and/or diarrhoea while taking RENITEC PLUS 20/6, or you have any of the following symptoms:
 - dry mouth, thirst
 - weakness, tiredness, drowsiness
 - muscle pains or cramps
 - fast heart beat
 - passing less urine than normalYou may be dehydrated because you are losing too much water. This may also drop your blood pressure too much.
- become pregnant while taking RENITEC PLUS 20/6.

Remind any doctor, dentist or pharmacist you visit that you are using RENITEC PLUS 20/6.

Things you should not do

- Do not give RENITEC PLUS 20/6 to anyone else, even if they have the same condition as you.

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, dizziness or light-headedness may be worse.

Looking after your medicine

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

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>heart/circulation-related:</p> <ul style="list-style-type: none"> • light-headedness or dizziness because blood pressure is too low <p>Respiratory-related:</p> <ul style="list-style-type: none"> • dry cough <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> • feeling sick (nausea), vomiting, loss of appetite • diarrhoea, constipation, stomach upset, pains or cramps <p>Mood-related:</p> <ul style="list-style-type: none"> • restlessness <p>Muscle-skeleton-related:</p> <ul style="list-style-type: none"> • muscle cramps <p>Eye-related:</p> <ul style="list-style-type: none"> • transient blurred vision or yellow vision <p>General conditions:</p> <ul style="list-style-type: none"> • headache • tiredness or weakness 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • 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 • Hydrochlorothiazide can cause breathing faster than normal or severe shortness of breath or difficulty breathing. Slightly blue fingertips and lips. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> • 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. • Hydrochlorothiazide may cause increased 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 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. 	<p>Tell your doctor immediately if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What RENITEC PLUS 20/6 contains

Active ingredients (main ingredient)	<ul style="list-style-type: none"> • enalapril maleate • hydrochlorothiazide
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • sodium bicarbonate • lactose monohydrate • maize starch • pregelatinised maize starch • indigo carmine • magnesium stearate
Potential allergens	<ul style="list-style-type: none"> • Lactose • RENITEC PLUS 20/6 does not contain gluten, sucrose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What RENITEC PLUS 20/6 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. (Aust R 73359).

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

Who distributes RENITEC PLUS 20/6

Organon Pharma Pty Ltd
 Level 5, 66 King St
 Sydney NSW 2000
 AUSTRALIA

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