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 Accuretic?

Accuretic contains the active ingredients quinapril hydrochloride and hydrochlorothiazide. Accuretic is used to lower high blood pressure (hypertension).

For more information, see Section 1. Why am I using Accuretic? in the full CMI.

2. What should I know before I use Accuretic?

Do not use if you have ever had an allergic reaction to Accuretic, any sulfonamide or sulfur medicines 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 Accuretic? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Accuretic 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 Accuretic?

For most patients, the usual starting dose is one Accuretic 10 mg/12.5 mg tablet a day. The dose may need to be increased to one Accuretic 20 mg/12.5 mg tablet a day, then two Accuretic 10 mg/12.5 mg tablets a day if necessary.

More instructions can be found in Section 4. How do I use Accuretic? in the full CMI.

5. What should I know while using Accuretic?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Accuretic. Make sure you drink enough water during exercise and hot weather, especially if you sweat a lot. Tell your doctor if you have excess vomiting and/or diarrhoea while taking Accuretic. Tell your doctor immediately if you feel light-headed or dizzy after taking your first dose of Accuretic, or when your dose is increased. Have your blood pressure checked when your doctor says, to make sure Accuretic is working. Regularly check your skin for any new or suspicious skin lesions.
Things you should not do	• Do not stop using this medicine, or change the dosage, without checking with your doctor.
Driving or using machines	Be careful driving or operating machinery until you know how Accuretic affects you.
Drinking alcohol	 If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Drinking alcohol may make these symptoms worse. If it does, reduce your consumption of alcohol. Your doctor may advise you to limit your alcohol intake.
Looking after your medicine	• Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Accuretic? in the full CMI.

6. Are there any side effects?

Side effects include feeling light-headed, dizzy or faint, dry cough, headache, nausea or vomiting, stomach pain, diarrhoea, constipation, tiredness or weakness, fatigue, sleepiness or drowsiness, impotence, runny or blocked nose, sneezing, loss of taste, confusion, restlessness, back pain, indigestion, sore throat, rash. For more serious side effects and further information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

Active ingredient(s): quinapril hydrochloride and hydrochlorothiazide (quin-a-pril hi-dro-clor-ride and hi-dro-clor-o-thigh-a-zide)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Accuretic. 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 Accuretic.

Where to find information in this leaflet:

- 1. Why am I using Accuretic?
- 2. What should I know before I use Accuretic?
- 3. What if I am taking other medicines?
- 4. How do I use Accuretic?
- 5. What should I know while using Accuretic?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Accuretic?

Accuretic contains the active ingredients quinapril hydrochloride and hydrochlorothiazide. Accuretic is a combination of a medicine called angiotensin converting enzyme (ACE) inhibitor and a diuretic "water tablet".

Accuretic is used to lower high blood pressure (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, including stroke, heart disease and kidney failure.

Accuretic works by:

- widening your blood vessels, which reduces pressure in the vessels, making it easier for your heart to pump blood around your body.
- making your kidneys pass more water and salt and retain more potassium. This helps reduce high blood pressure.

2. What should I know before I use Accuretic?

Warnings

Do not use Accuretic if:

 you are allergic to quinapril hydrochloride or hydrochlorothiazide, any sulfonamide or sulfur medicines, or any of the ingredients listed at the end of this leaflet

One of the active ingredients of Accuretic, hydrochlorothiazide, is a sulfur-containing medicine (a sulfonamide). Therefore, if you are allergic to sulfur medicines, such as some antibiotics, you are likely to be allergic to Accuretic. Check with your doctor or pharmacist if you are not sure whether you are allergic to sulfur medicines.

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

Always check the ingredients to make sure you can use this medicine

 you have taken any other 'ACE inhibitor' medicine 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 Accuretic.

- 3. you or your family have a history of swelling of the face, lips, tongue, throat, hands or feet for no apparent reason
- 4. you have kidney problems or a condition called 'renal artery stenosis'
- 5. you have regular dialysis for blood filtration
- you are currently taking a blood pressure lowering medicine containing aliskiren or with medicines known as angiotensin receptor blockers (ARB) or other ACE inhibitors and you have the following conditions:
- diabetes
- kidney problems
- high levels of potassium in your blood
- congestive heart failure.
- you are currently taking a neutral endopeptidase inhibitor, used to treat high blood pressure or heart failure

Taking Accuretic with a neutral endopeptidase inhibitor (e.g. sacubitril/ valsartan combination) increases your risk of angioedma, rapid swelling of your face, lips, mouth, tongue or throat and may result in difficulty in swallowing or breathing.

8. you are pregnant or breastfeeding

Accuretic may enter your womb or it may pass into the breast milk and there is the possibility that your baby may be affected.

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

Check with your doctor if you:

 have any allergies to any other medicines, foods, preservatives or dyes

- have any other medical conditions, especially the following:
 - o kidney problems, or are having dialysis
 - o liver problems
 - o heart problems
 - low blood pressure, which you may notice as dizziness or light-headedness
 - o diabetes
 - o high levels of potassium in your blood
 - o gout
 - o high cholesterol
 - Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune diseases
 - o non-melanoma skin cancer
 - psoriasis (red patches on your skin) or worsening of already existing psoriasis.
- have previously had trouble breathing, fever, or low blood pressure after taking hydrochlorothiazide
- are following a very low salt diet
- are about to receive desensitisation therapy for an allergy
- are about to undergo dialysis or lipoprotein apheresis
- are about to have surgery or a general anaesthetic
- take any medicines for any other condition.

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

If you become pregnant while taking Accuretic, tell your doctor immediately.

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Children

The safety and effectiveness of Accuretic in children have 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 Accuretic and affect how it works.

Tell your doctor or pharmacist if you are taking any of the following:

- other medicines used to treat high blood pressure
- other medicines that work in a similar fashion to ACE inhibitors, such as Angiotensin Receptor Blockers (these are used to treat high blood pressure and/or heart failure)
- digoxin, a medicine used to treat heart failure
- neutral endopeptidase inhibitor (e.g. sacubitril/valsartan combination), a medicine used to treat high blood pressure or heart failure.
- other diuretics, also known as fluid or water tablets
- non-steroidal anti-inflammatory drugs (NSAIDs) or Cox-2 inhibiting medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- allopurinol, a medicine used to treat gout

- potassium supplements or potassium-containing salt substitutes
- lithium, a medicine used to treat mood swings and some types of depression
- tetracycline antibiotics
- trimethoprim or trimethoprim/sulfamethoxazole, medicines used to treat bacterial infections
- any other antibiotics and medicines to treat infections
- 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
- cholestyramine and colestipol, used to treat high cholesterol
- medicines used to relax muscles before and during surgery
- medicines used in emergency situations such as adrenaline.

Tell your doctor if you are taking any of the following blood pressure lowering medicines:

- angiotensin II receptor blocker (ARB)
- aliskiren.

For some patients, Accuretic should not be taken in combination with these medicines.

Your doctor may check your kidney function, blood pressure and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Tell your doctor if you are taking any of the following medicines:

- mTOR inhibitors (e.g. temsirolimus), used in the treatment of kidney cancer
- DPP-IV inhibitors (e.g. vildagliptin), used in the treatment of diabetes.

Taking Accuretic in combination with these medicines may increase your risk of having an allergic reaction.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Accuretic.

4. How do I use Accuretic?

How much to take

- for most patients, the usual starting dose is one Accuretic 10 mg/12.5 mg tablet a day
- the dose may need to be increased to one Accuretic 20 mg/12.5 mg tablet a day, then two Accuretic 10 mg/12.5 mg tablets a day if necessary
- most patients take between 10 mg/12.5 mg to 20 mg/12.5 mg daily
- each dose may be taken once a day
- follow the instructions provided and use Accuretic until your doctor tells you to stop.

When to take Accuretic

 take Accuretic at about the same time each day, with or without food

Taking it at the same time each day will have the best effect. It will also help you remember when to take the tablets.

It does not matter whether you take it with or without food.

How to take Accuretic

- swallow the tablets whole with a full glass of water
- do not chew the tablets.

If you forget to use Accuretic

Accuretic should be used regularly at the same time each day.

If it is almost time for 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 medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

If you use too much Accuretic

If you think that you have used too much Accuretic, you may need urgent medical attention.

You should immediately:

- telephone 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.

5. What should I know while using Accuretic?

Things you should do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Accuretic.

Make sure you drink enough water during exercise and hot weather when you are taking Accuretic, especially if you sweat a lot.

If you do not drink enough water while taking Accuretic, you may feel faint, light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

Tell your doctor if you have excess vomiting and/or diarrhoea while taking Accuretic, 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 normal.

You may be dehydrated because you are losing too much water.

If you are going to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Accuretic.

Your blood pressure may drop suddenly.

If you are about to have any blood tests, tell your doctor that you are taking Accuretic.

Accuretic may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure Accuretic is working.

Regularly check your skin for any new or suspicious skin lesions. It has been observed that one of the ingredients in Accuretic may increase the risk of non-melanoma skin cancer if used at a high dose, or for an extended period.

Limit sun exposure and use adequate sun protection to minimise risk.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Call your doctor straight away if you feel light-headed or dizzy after taking your first dose of Accuretic, or when your dose is increased.

Things you should not do

- do not stop using this medicine suddenly, or change the dosage, without checking with you doctor
- do not give your medicine to anyone else, even if they have the same condition as you
- do not take Accuretic to treat any other complaints unless your doctor or pharmacist tells you to.

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.

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.

Diet

Eat a healthy diet which includes plenty of fresh vegetables, fruit, bread (preferably wholegrain), cereals and fish. Also eat less sugar and fat (especially saturated fat) which includes sausages, fatty meats, full cream dairy products, biscuits, cakes, pastries, chocolates, chips and coconut. Monounsaturated and polyunsaturated fats from olive oil, canola oil, avocado and nuts are beneficial in small quantities.

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 and avoid cooked or processed foods containing high sodium (salt) levels.

Exercise

Regular exercise, maintained over the long term, helps to reduce blood pressure and helps get the heart fitter. Regular exercise also improves your blood cholesterol levels, helps reduce your weight and stress levels, and improves your sleep, mood and ability to concentrate. However, it is important not to overdo it. Before starting any exercise, ask your doctor about the best kind of programme for you.

Smoking

Your doctor may advise you to stop smoking or at least cut down. Ask your doctor or pharmacist for further information and advice.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Accuretic affects you.

As with other medicines in this class, Accuretic may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to Accuretic before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If this occurs do not drive. If you drink alcohol, dizziness or lightheadedness may be worse.

Drinking alcohol

Be careful if you feel light-headed, dizzy or faint when getting out of bed or standing up. It is suggested you get up slowly.

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 continues or gets worse, talk to your doctor.

Drinking alcohol may make these symptoms worse. If it does, reduce your consumption of alcohol.

Looking after your medicine

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions on 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.

Do not use this medicine after the expiry date.

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.

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.

Mild side effects

Mild side effects	What to do
 feeling light-headed, dizzy or faint dry cough headache feeling sick (nausea) or vomiting 	Speak to your doctor if you have any of these mild side

Mild side effects		What to do
•	stomach pain	effects and
•	diarrhoea	they worry you.
•	constipation	
•	unusual tiredness or weakness,	
	fatigue	
•	sleepiness or drowsiness	
•	difficulty in getting or maintaining	
	an erection (impotence)	
•	runny or blocked nose, or	
	sneezing	
•	taste disturbances or loss of taste	
•	confusion or nervousness	
•	restlessness	
•	back pain	
•	indigestion	
•	sore throat and discomfort when	
	swallowing	
•	rash	
		1

Serious side effects

Serious side effects		What to do
Se • • •	rious side effects eye pain, vision problems blurred vision or yellow vision itchy or raised skin rash, hives or nettle rash muscle cramps symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal signs of anaemia such as tiredness, being short of breath and looking pale tingling or numbness in the hands, feet or ankles severe upper stomach pain, often with nausea and vomiting	What to do Call your doctor as soon as possible if you notice any of these serious side effects.
• • •	signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers aching, tender or weak joints or muscles not caused by exercise passing little or no urine swelling of the hands, feet or ankles bleeding or bruising more easily than normal yellowing of the skin and/or eyes	

new or suspicious skin lesions

More serious side effects	What to do
 fainting within a few hours of taking a dose 	Call your doctor straight
fast or irregular heart beat	away, or go
• shortness of breath or tightness in	straight to the
the chest	Emergency
 sudden or general weakness, or 	Department at
weakness in the arms or legs	your nearest

Мо	re serious side effects	What to do
•	sudden onset of stomach pains or cramps with or without nausea or vomiting pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centered marks severe flaking or peeling of the skin severe blisters and bleeding in the lips, eyes, mouth, nose and genitals severe skin reaction which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell chest pain loss of vision; may be temporary or more gradual	hospital if you notice any of these more serious side effects.
•	swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.	Stop taking Accuretic as well

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 <u>www.tga.gov.au/</u> <u>reporting-problems</u>. 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 Accuretic contains

Active ingredients (main ingredient)	Accuretic 10 mg/12.5 mg - 10 mg quinapril hydrochloride and 12.5 mg hydrochlorothiazide per tablet Accuretic 20 mg/12.5 mg - 20 mg quinapril hydrochloride and 12.5 mg hydrochlorothiazide per tablet
Other ingredients (inactive ingredients)	crospovidone lactose monohydrate magnesium carbonate hydrate magnesium stearate povidone

Opadry Pink OY-S-6937
ne if you are allergic to any of
ke
- pink, oval, biconvex, film-coatec des
- pink, triangular, biconvex, film- one side
ns 30 tablets.
tic
875 229 ation.com.au

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