

ACCURETIC®

Quinapril hydrochloride and Hydrochlorothiazide

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Accuretic.

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 Accuretic against the benefits it is expected to 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 Accuretic is used for

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.

How Accuretic works

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.

Accuretic also works by making your kidneys pass more water and salt and retain more potassium. This helps reduce high blood pressure.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

Use in Children

The safety and effectiveness of Accuretic in children have not been established.

Before you take Accuretic

When you must not take it

Do not take Accuretic if you have an allergy to:

- any medicine containing quinapril hydrochloride or hydrochlorothiazide
- any of the ingredients listed at the end of this leaflet

- any sulfonamide or sulfur medicines.

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.

Do not take Accuretic if:

- 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.

- you or your family have a history of swelling of the face, lips, tongue, throat, hands or feet for no apparent reason
- you have kidney problems or a condition called 'renal artery stenosis'
- you have regular dialysis for blood filtration.

You may experience an allergic reaction.

Do not take Accuretic if 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 may experience severe side effects.

Do not take Accuretic if 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.

Do not take Accuretic after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney problems, or are having dialysis
- liver problems
- heart problems
- low blood pressure, which you may notice as dizziness or light-headedness
- diabetes
- high levels of potassium in your blood
- gout
- high cholesterol
- Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune diseases.

You must also tell your doctor if you:

- 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
- plan to become pregnant or breastfeed.

If you have not told your doctor about any of the above, tell him/her before you start taking Accuretic.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Accuretic or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

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
- 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.

If you are not sure if you are taking any of the medicines mentioned in this leaflet, check with your doctor or pharmacist.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Accuretic.

How to take Accuretic

Follow all directions given to you by your doctor or pharmacist 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 much to take

Your doctor or pharmacist will tell you how many Accuretic tablets you need to take each day. This may depend on your condition and whether or not you are taking any other medicines.

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.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew the tablets.

When to take it

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 long to take it

Continue taking your medicine for as long as your doctor tells you.

Accuretic helps control your condition, but does not cure it. It is important to keep taking your medicine every day even if you feel well.

If you forget to take it

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 that you missed.

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

If you are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Australian Poisons Information Centre (telephone 13 11 26) or the New Zealand National Poisons Information Centre (telephone 0800 POISON or 0800 764 766), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Accuretic.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Accuretic, you may feel light-headed, dizzy or you may faint. You may also become thirsty, confused, have a change in the amount of urine passed or have a fast heartbeat.

While you are taking Accuretic

Things you must 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.

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

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 become pregnant while taking Accuretic, tell your doctor immediately.

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.

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.

Things you must not do

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.

Do not stop taking Accuretic, or change the dosage, without checking with your doctor.

Things to be careful of

If you feel light-headed, dizzy or faint when getting out of bed or standing up, 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.

Be careful driving or operating machinery 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 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.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Accuretic.

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.

It can be difficult to tell whether side effects are the result of taking Accuretic, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

If you are over 65 years of age you may have an increased chance of getting side effects.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if...

Ask your doctor or pharmacist for advice if you notice any of the following and they worry you:

- feeling light-headed, dizzy or faint
- dry cough
- headache
- feeling sick (nausea) or vomiting
- stomach pain
- diarrhoea
- 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.

These side effects are usually mild. All side effects should be reported to a health professional.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any of the following:

- 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
- 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.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Go to hospital if...

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- fainting within a few hours of taking a dose
- fast or irregular heart beat
- shortness of breath or tightness in the chest
- sudden or general weakness, or weakness in the arms or legs
- 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-centred 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.

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

Stop taking Accuretic and tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice the following:

- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking Accuretic

Storage

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

If you take the tablets out of the box they may not keep well.

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

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

Do not leave it on a windowsill or in the car on hot days.

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 or pharmacist tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Accuretic tablets come in two strengths and each has a different appearance:

- Accuretic 10 mg/12.5 mg - Pink, oval, biconvex, film-coated tablets, scored on both sides
- Accuretic 20 mg/12.5 mg - Pink, triangular, biconvex, film-coated tablets, scored on one side

A box of Accuretic contains 30 tablets.

Ingredients

Active ingredients:

- 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:

- crospovidone
- lactose
- magnesium carbonate
- magnesium stearate
- povidone
- candelilla wax
- Opadry Pink OY-S-6937.

Accuretic does not contain sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Accuretic is supplied in Australia by:

Pfizer Australia Pty Ltd

ABN 50 008 422 348

38-42 Wharf Road

West Ryde NSW 2114

Australia

Toll Free Number: 1800 675 229

Accuretic is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland

New Zealand

Toll Free Number: 0800 736 363

Australian Registration Numbers

Accuretic 10 mg/12.5 mg - AUST R 81930

Accuretic 20 mg/12.5 mg - AUST R 81931

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