

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 Accupril?

Accupril contains the active ingredient quinapril hydrochloride. Accupril is used to lower high blood pressure (hypertension). It is also used to treat heart failure.

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

2. What should I know before I use Accupril?

Do not use if you have ever had an allergic reaction to Accupril, another ACE inhibitor, 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 Accupril? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Accupril 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 Accupril?

For high blood pressure, the usual starting dose is 5 mg to 10 mg taken once a day. The dose may need to be increased. Most patients take between 10 mg and 40 mg each day. For heart failure, the usual starting dose is 5 mg taken once a day. In most patients, effective doses are between 10 mg and 20 mg a day.

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

5. What should I know while using Accupril?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Accupril. 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 Accupril. Tell your doctor immediately if you feel light-headed or dizzy after taking your first dose of Accupril, or when your dose is increased. Have your blood pressure checked when your doctor says, to make sure Accupril is working. 	
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 Accupril 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 Accupril? 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, drowsiness, sleepiness, hair loss or thinning, dry mouth or throat, taste disturbance or loss of taste, confusion or nervousness, back pain, rash or impotence. For more serious side effects and further information, including what to do if you have any side effects, see Section <u>6</u>. Are there any side effects? in the full CMI.

Active ingredient(s): quinapril hydrochloride (quin-a-pril hi-dro-clor-ride)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Accupril. 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 Accupril.

Where to find information in this leaflet:

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

1. Why am I using Accupril?

Accupril contains the active ingredient quinapril hydrochloride, an angiotensin converting enzyme (ACE) inhibitor.

Hypertension

Accupril 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.

Heart Failure

Accupril is also used to treat heart failure. Heart failure means that the heart muscle is weak and cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops.

Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

Accupril works by widening your blood vessels, which reduces pressure in the vessels, making it easier for your heart to pump blood around your body. This helps increase the supply of oxygen to your heart, so that when you place extra demands on your heart, such as during exercise, your heart may cope better and you may not get short of breath as easily.

2. What should I know before I use Accupril?

Warnings

Do not use Accupril if:

 you have an allergy to Accupril or any other medicine containing quinapril, or any of the ingredients listed at the end of this leaflet

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
- 3. you or your family have a history of swelling of the face, lips, tongue, throat, hands or feet for no apparent reason

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

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to Accupril.

Use of ACE inhibitors have been associated with Syndrome of Inappropriate Anti-diuretic Hormone (SIADH) and subsequent low blood sodium levels.

Your doctor may also wish to do a blood test to monitor your sodium levels to ensure they are within normal limits. In the elderly and other at risk patients, sodium levels may be monitored more frequently.

- 4. you have kidney problems or a condition called 'renal artery stenosis'
- 5. you have regular dialysis for blood filtration
- 6. 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.
- 7. you have chronic heart failure and you are taking sacubitril/valsartan combination (e.g. Entresto®), a neutral endopeptidase inhibitor. Taking Accupril with this medicine increases your risk of angioedema, which includes rapid swelling of your face, lips, mouth, tongue or throat and may result in difficulty swallowing or breathing.
- 8. you are pregnant or breastfeeding

Accupril 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, or have had, 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
 - psoriasis (red patches on your skin) or worsening of already existing psoriasis.
- 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</u>. Are there any side effects?

Pregnancy and breastfeeding

If you become pregnant while taking Accupril, 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 Accupril 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 Accupril 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)
- 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
- 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.

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

- angiotensin II receptor blocker (ARB)
- aliskiren.

For some patients, Accupril 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 Accupril 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 Accupril.

4. How do I use Accupril?

How much to take

For high blood pressure

- for most patients, not on diuretics, the usual starting dose is 5 mg to 10 mg taken once a day
- the dose may need to be increased depending upon your blood pressure at an interval of 4 weeks
- most patients take between 10 mg and 40 mg each day.

For heart failure

- the usual starting dose is 5 mg taken once a day
- in most patients, effective doses are between 10 mg and 20 mg a day

When to take Accupril

- your doctor will advise whether the dose is to be taken as a single dose or as two separate doses (one in the morning and one at night).
- take Accupril at about the same time each day

 Taking it at the same time each day will have the

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

take Accupril before meals

Food with a high fat content may interfere with the absorption of Accupril.

How to take Accupril

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

If you forget to use Accupril

Accupril 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 Accupril

If you think that you have used too much Accupril, 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 Accupril?

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 Accupril.

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

If you do not drink enough water while taking Accupril, 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 or diarrhoea while taking Accupril.

You may lose too much water and salt and your blood pressure may drop too much.

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

This is especially important if you are taking Accupril for heart failure.

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

Your blood pressure may drop suddenly.

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

Accupril may interfere with the results of some tests as it can result in sodium blood levels that are lower than the normal limits.

Have your blood pressure checked when your doctor says, to make sure Accupril 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 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 Accupril to treat any other complaints unless your doctor or pharmacist tells you to.

Things that would be helpful for your blood pressure or heart failure

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 Accupril affects you.

As with other ACE inhibitor medicines, Accupril may cause dizziness, light-headedness or tiredness in some people. Make sure you know how you react to Accupril 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.

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 stomach pain diarrhoea constipation unusual tiredness or weakness, fatigue feeling drowsy or sleepy during the day hair loss or thinning dry mouth or throat taste disturbances or loss of taste confusion or nervousness back pain rash difficulty in getting or maintaining an erection (impotence) 	Speak to your doctor if you have any of these mild side effects and they worry you.

Serious side effects

Serious side effects	What to do
 disturbed vision symptoms of sunburn (such as redness, itching, swelling, 	Call your doctor as soon as possible if you notice

Serious side effects	What to do
blistering) which may occur more quickly than normal itchy, raised or red skin rash	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 feelings of deep sadness and unworthiness (depression) severe upper stomach pain, often with nausea and vomiting passing little or no urine bleeding or bruising more easily than normal. 	

More serious side effects

More serious side effects	What to do
 fainting within a few hours of taking a dose fast or irregular heart beat shortness of breath or tightness in the chest 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 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these more serious side effects. Stop taking Accupril as
 genitals chest pain swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing. 	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 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 Accupril contains

Active ingredients (main ingredient)	Accupril 5 mg - 5 mg quinapril hydrochloride per tablet Accupril 10 mg - 10 mg quinapril hydrochloride per tablet Accupril 20 mg - 20 mg quinapril hydrochloride per tablet
Other ingredients (inactive ingredients)	magnesium carbonate hydrate lactose monohydrate gelatin crospovidone magnesium stearate candelilla wax Opadry complete film coating system Y-5-9020 Brown OPADRY Y-5-9020G

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

What Accupril looks like

Accupril 5 mg - reddish-brown, oval, biconvex, film-coated tablet with bisecting score on both sides and debossing "5" on both sides in opposite direction AUST R 40926

Accupril 10 mg - Reddish-brown, triangular, biconvex film-coated tablet with bisecting score on both sides and debossing "10" on one side AUST R 40928

Accupril 20 mg - Reddish-brown, round, biconvex film-coated tablet, with bisecting score on both sides and debossing "20" on one side $\,$

AUST R 40930

A box of Accupril contains 30 tablets.

Who distributes Accupril

Pfizer Australia Pty Ltd

Sydney NSW

Toll Free Number: 1800 675 229 www.pfizermedicalinformation.com.au

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