

QPRIL

contains the active ingredient *quinapril hydrochloride*

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about QPRIL.

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 QPRIL 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 QPRIL is used for

QPRIL is used to lower high blood pressure (hypertension). It is also used to treat heart failure.

Hypertension:

QPRIL 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:

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 working. 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.

How QPRIL works

One of the ways QPRIL helps lower blood pressure and treat heart failure is that it widens blood vessels which reduces pressure in the 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. This helps increase the supply of oxygen to your heart and it also means that when you place extra demands on your heart, such as during exercise, your heart may cope better so you may not get short of breath as easily.

QPRIL belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors.

Your doctor may have prescribed QPRIL for another reason.

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

QPRIL is not addictive.

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

Use in Children

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

Before you take QPRIL

When you must not take it

Do not take QPRIL if:

- **you have an allergy to QPRIL, or other brands of quinapril hydrochloride, or any of the ingredients listed at the end of this leaflet.**
- **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 QPRIL.
- 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 elderly and other at risk patients sodium levels may be monitored more frequently

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

Do not take QPRIL if:

- **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 QPRIL if you are diabetic or have kidney problems and are currently taking a medicine called 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 QPRIL if you are pregnant or breast-feeding.

QPRIL may be absorbed into the womb or enter from breast milk and therefore there is a possibility that your baby may be affected.

Do not take QPRIL 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 QPRIL, talk to your doctor.

Before you start to take it

Tell your doctor if:

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

QPRIL should not be used during pregnancy or while breast-feeding.

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

- kidney problems, or you are undergoing dialysis
- heart problems
- liver problems
- low blood pressure, which you may notice as dizziness or light-headedness
- diabetes
- high levels of potassium in your blood

3. you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.

You must also tell your doctor if you:

- you are following a very low salt diet
- have a family history of swelling of the face, lips, tongue, throat, hands or feet
- are about to receive desensitisation therapy for an allergy
- are able 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 them before you start to take any QPRIL.

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 that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and QPRIL may interfere with each other. These include:

- other medicines used to treat high blood pressure
- other medicines that work in a similar way to ACE inhibitors such as Angiotensin Receptor Blockers (these are used to treat high blood pressure and/or heart failure)
- diuretics, used to decrease swelling of the ankles, feet or legs (oedema). These tablets are also known as fluid or water tablets. Tell your doctor if you are taking other medicines like diuretic tablets for high blood pressure so as to make sure that the combination does not cause a sudden and excessive drop in blood pressure
- non-steroidal anti-inflammatory medicines (NSAIDs) or COX 2 inhibiting medicines used to relieve pain, swelling and other symptoms of inflammation including arthritis
- medicines used to reduce the build up of fluid around the abdomen (ascites) due to liver disease
- medicines used to help treat certain heart conditions
- lithium, a medicine used to treat mood swings and some types of depression
- potassium supplements or potassium-containing salt substitutes,
- 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, QPRIL 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.
- NEP inhibitors (e.g. sacubitril/valsartan), used in the treatment of congestive heart failure

Taking QPRIL 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 QPRIL,

How to take QPRIL

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.

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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 QPRIL only when prescribed by your doctor.

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 on your blood pressure at an interval of 4 weeks. Most patients take between 10 mg and 40 mg each day. This dose may be taken once a day or divided into two equal doses per day (one in the morning and one at night).

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. Your doctor will advise whether the dose is to be taken as a single dose or as two separate doses.

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 QPRIL at about the same time each day.

Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

Take QPRIL before food.

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

Swallow QPRIL with a glass of water.

How long to take it

Continue taking QPRIL for as long as your doctor tells you to.

QPRIL helps control your condition, but does not cure it. Therefore QPRIL must be taken every day.

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 tablet(s) 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 have trouble remembering to take your tablets, ask your pharmacist for some hints.

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

If you take too much (overdose)

Immediately telephone your doctor or the Australian 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 QPRIL. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much QPRIL, you will probably feel light-headed or dizzy, or you may faint.

While you are using QPRIL

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking QPRIL.

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

If you feel any light-headedness or dizziness after you take your first dose of QPRIL or if your dose is increased, tell your doctor immediately. This is especially important if you are taking QPRIL for heart failure.

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

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking QPRIL.

Your blood pressure may drop suddenly.

If you are about to have any blood pressure tests, tell your doctor that you are taking QPRIL. QPRIL may interfere with the result in the sodium blood levels that are lower than the normal limits.

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

If you do not drink enough water while taking QPRIL, 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 have excessive vomiting and/or diarrhoea while taking QPRIL, tell your doctor.

This can also mean that you are losing too much water and salt, and may drop your blood pressure too much.

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 QPRIL to anyone else, even if they have the same condition as you.

Do not take QPRIL to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking QPRIL, or lower the dosage, without checking with your doctor.

Do not give QPRIL to children. The safety and effectiveness of QPRIL in this group has not been proven.

Things to be careful of

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

You may feel light-headed or dizzy, especially if you are also taking a diuretic (fluid tablet). 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.

Be careful driving or operating machinery until you know how QPRIL affects you.

QPRIL may cause dizziness, tiredness 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 QPRIL 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 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 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 vegetables and fruit, bread (preferably wholegrain), cereal 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, 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.

For more information and tools to improve your heart health, call Heartline, the Heart Foundation's national telephone information service, on 1300 36 27 87 (local call cost).

Know warning signs of heart attack and what to do:

- Tightness, fullness, pressure, squeezing, heaviness or pain in your chest, neck, jaw, throat, shoulders, arms or back.
- You may also have difficulty breathing, or have a cold sweat or feel dizzy or light headed or feel like vomiting (or actually vomit).
- If you have heart attack warning signs that are severe, get worse or last for 10 minutes even if they are mild, call triple zero (000). Every minute counts.

Side effects

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

QPRIL helps most people with high blood pressure and heart failure, 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.

It can be difficult to tell whether side effects are the result of taking QPRIL, 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.

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

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- light-headedness, dizziness or faint because your blood pressure may be too low
- headache
- dry cough
- feeling sick (nausea) or vomiting
- Stomach pain
- diarrhoea
- constipation
- unusual tiredness or weakness, or fatigue
- feeling drowsy or sleepy during the day
- feelings of deep sadness and unworthiness (depression)
- 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

These are usually mild side effects of QPRIL, but may be serious.

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

- disturbed vision
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- itchy, raised or red skin rash or other skin problems
- aching, tender or weak joints or muscles not caused by exercise

- feelings of deep sadness and unworthiness (depression)
- fast or irregular heart beat
- shortness of breath or tightness in the chest
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- severe upper stomach pain, often with nausea and vomiting
- passing little or no urine
- bleeding or bruising more easily than normal

These may be serious side effects. You may need urgent 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 chest

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

sudden onset of stomach pains or cramps with or without nausea or vomiting

severe flaking or peeling of skin

severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
chest pain

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

Stop taking QPRIL 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 any other effects that is making you feel unwell.

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

After using QPRIL

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 crumbly.

Keep it 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 windowsills.

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 QPRIL 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

QPRIL comes in four strengths of tablets:

- QPRIL 5 mg tablets: Beige oval coated tablets, marked "QP" scoreline "5" on one side and "G" on the other side.
- QPRIL 10 mg tablets: Beige oval coated tablets, marked "QP"

scoreline "10" on one side and "G" on the other side.

- QPRIL 20 mg tablets: Beige round coated tablets, marked "QP" scoreline "20" on one side and "G" on the other side.

A box of QPRIL contains 30 tablets.

Ingredients

Active ingredient:

- QPRIL 5 mg - 5 mg quinapril (as hydrochloride) per tablet
- QPRIL 10 mg - 10 mg quinapril (as hydrochloride) per tablet
- QPRIL 20 mg - 20 mg quinapril (as hydrochloride) per tablet

Inactive ingredients:

- microcrystalline cellulose
- lactose monohydrate
- magnesium oxide
- crospovidone
- magnesium stearate
- Opadry YS-1-17164

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

QPRIL contains sugars (as lactose).

Supplier

QPRIL is supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.mylan.com.au

Australian Register Numbers:

QPRIL 5 - AUST R 96915
QPRIL 10 - AUST R 96923
QPRIL 20 - AUST R 96924
QPRIL 40 - AUST R 96925

Not all strengths are available.

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