

APO-Quinapril

Quinapril hydrochloride

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about quinapril. 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 this medicine 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 this medicine is used for

Quinapril is used to lower high blood pressure (also known as hypertension) and treat heart failure.

High blood pressure:

Everyone has blood pressure. Blood pressure helps to move your blood all around your body. Your blood pressure may be different at different times of the day and may be affected by how busy or worried you are. You have 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 high blood pressure. The only way of knowing that you have high blood pressure 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. 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 it works

Quinapril belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

Quinapril works by widening your blood vessels, which reduces pressure in the vessels and makes it easier for your heart to pump blood around your body. This increases 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.

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

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

Use in children

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

Before you take it

When you must not take it

Do not take this medicine if:

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

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.

Do not take this medicine if:

- you have kidney problems or a condition known as 'severe renal artery stenosis'
- you have a certain type of dialysis for blood filtration (using 'AN69' membranes). Check with your doctor before taking quinapril if you are receiving dialysis.

You may experience an allergic reaction.

Do not take quinapril if you are currently taking 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 this medicine if you are pregnant, plan to become pregnant or are breastfeeding.

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

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

If it has expired or is damaged, return it to your pharmacist for disposal.

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, foods, preservatives or dyes.

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

- kidney problems, or are having dialysis
- heart problems
- low blood pressure (hypotension), which you may notice as dizziness or light-headedness
- liver problems
- diabetes
- high level of potassium in your blood.

You must also tell your doctor if you:

- are following a very low salt diet
- are about to receive de-sensitisation therapy for an hymenoptera (insect) allergy
- are about to undergo dialysis or lipoprotein apheresis
- are planning to have surgery, dental treatment or an anaesthetic
- plan to become pregnant or breastfeed.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

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 quinapril 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 or heart failure
- 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, used to treat mood swings and some types of depression
- certain medicines used to treat bacterial and fungal infections, such as 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, quinapril 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, used in the treatment of kidney cancer (e.g. temsirolimus)
- DPP-IV inhibitors, used in the treatment of diabetes (e.g. vildagliptin)
- NEP inhibitors (e.g. sacubitril/valsartan), used in the treatment of congestive heart failure.

Taking quinapril 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 these medicines mentioned in this leaflet, check with your doctor or pharmacist.

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

How to take this medicine

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 will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

For high blood pressure:

For most patients, the usual starting dose is 5 mg to 10 mg taken once a day. The dose may need to be adjusted 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 in the 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 (one in the morning and one in the night).

How to take it

Swallow the tablets whole with a full glass of water. Do not chew the tablets.

When to take it

Take your medicine at about the same time each day.

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

Take this medicine before meals.

Taking quinapril with food that has a high fat content may mean it does not work as well.

How long to take it

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

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take 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 Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much quinapril, you may feel light-headed, dizzy or you may faint.

While you are using this medicine

Things you must do

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

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

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

Tell your doctor or dentist if you are going to have surgery or an anaesthetic or are going into hospital.

Your blood pressure may drop suddenly.

Tell your doctor if you are about to have any blood tests.

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

Keep all of your doctor's appointments so that your progress can be checked.

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

Tell your doctor if you have experienced excess vomiting or diarrhoea.

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

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

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

If you do not drink enough water while taking quinapril, 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.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaints unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Things to be careful of

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

As with other ACE inhibitor medicines. Quinapril may cause dizziness, light-headedness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. If you drink alcohol, dizziness or light-headedness may be worse.

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.

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 reduce blood pressure and helps get the heart fitter. Regular exercise also improves your cholesterol levels, helps reduce your weight and stress levels, and

improved 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 quinapril.

This medicine 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 attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking quinapril, 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 following lists 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 or pharmacist if you notice any of the following and they worry you:

- feeling light-headed, dizzy or faint
- headache
- dry cough

- stomach complaints, such as feeling sick (nausea) or vomiting, stomach pain, diarrhoea, constipation
- aching, tender or weak joints or muscles not caused by exercise
- 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.

The above list includes the more common side effects of your medicine. They are usually mild.

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
- feelings of deep sadness and unworthiness (depression)
- itchy, raised or red skin rash
- 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.
- aching, tender or weak joints or muscles not caused by exercise

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

If any of the following happen, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fainting within a few hours of taking a dose
- fast or irregular heartbeat
- shortness of breath or tightness in the chest
- sudden onset of stomach pains or cramps with or without nausea or vomiting
- severe flaking or peeling of the skin
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- chest pain.

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

Stop taking quinapril 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 occur in some patients.

Storage and Disposal

Storage

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of the pack it may not keep well.

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

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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 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

Quinapril 5 mg tablets:

Yellow coloured, oval shaped, film-coated tablets debossed with '5' on one side and scoreline on the other side.

Quinapril 10 mg tablets:

Yellow coloured, Capsule shaped, film-coated tablets debossed with '10' on one side and scoreline on the other side.

Quinapril 20 mg tablets:

Yellow coloured, circular, film-coated tablets debossed with '20' on one side and scoreline on the other side.

Quinapril is available in blister packs of 30 tablets.

Not all strengths may be available.

APO-Quinapril 10 mg tablets (blister pack), AUST R 133220.

APO-Quinapril 20 mg tablets (blister pack), AUST R 133221.

Ingredients

Each tablet contains 5 mg, 10 mg or 20 mg of quinapril hydrochloride as the active ingredient.

It also contains the following inactive ingredients:

- magnesium carbonate hydrate
- calcium sulfate dehydrate
- colloidal anhydrous silica

- crospovidone
- povidone
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- purified talc
- lecithin
- iron oxide yellow
- xanthan gum.

This medicine does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

This medicine is supplied in Australia by:

Apotex Pty Ltd

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Tel: (02) 8877 8333

Web: www1.apotex.com/au

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