

APO-Quinapril

Contains the active ingredient, quinapril (as quinapril hydrochloride)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Quinapril. It contains the active ingredient quinapril (as quinapril hydrochloride).

It is used to:

- lower high blood pressure (hypertension).
- treat heart failure.

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.

Hypertension (high blood pressure):

Blood pressure helps get 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 hypertension 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. 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 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.

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

Your doctor may have prescribed quinapril for another reason. Ask your doctor if you have any questions about why quinapril has been prescribed for you.

There is no evidence that this medicine is addictive.

Use in children

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

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are diabetic or have kidney problems and are currently taking a medicine called aliskiren. This medicine is used to treat high blood pressure.**
- **You have or have had any of the following:**
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.
A kidney condition known as 'severe renal artery stenosis'.
A certain type of dialysis for blood filtration (using 'AN69' membranes). Please check with your doctor before taking quinapril if you are receiving dialysis.
- **You are pregnant, planning to become pregnant or you are not using an effective contraceptive.** Quinapril may affect your developing baby if you take it during pregnancy.
- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You are hypersensitive to, or have had an allergic reaction to, quinapril or any of the**

ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin; fainting or hayfever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney problems, including a condition known as 'renal artery stenosis'
 - you are about to undergo dialysis or lipoprotein apheresis.
 - you have recently experienced vomiting or diarrhoea
 - heart problems
 - low blood pressure (hypotension)
 - liver problems
 - diabetes
 - high level of potassium in your blood.
3. You are following a very low salt diet
4. You are about to receive desensitisation therapy for an hymenoptera (insect) allergy
5. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant.
6. You are currently breast-feeding or you plan to breast-feed. Do not

take this medicine whilst breast-feeding.

7. You are planning to have surgery or an anaesthetic.
8. You are currently receiving or are planning to receive dental treatment.
9. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with quinapril. These include:

- 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 II 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
- injectable gold (sodium aurothiomalate)
- tetracycline antibiotics
- certain medicines used to treat bacterial and fungal infections
- mTOR inhibitors (e.g. temsirolimus), used in the treatment of kidney cancer
- DPP-IV inhibitors (e.g. vildagliptin), used in the treatment of diabetes.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with quinapril.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

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.

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

For hypertension (high blood pressure):

For most patients, not on diuretics, the usual starting dose is 5 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 and 40 mg each day.

This dose may be taken once a day or divided into two equal doses per day.

For heart failure:

The usual starting dose is 5 mg taken once a day. In most patients, effective doses are between 10 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.

How to take it

Swallow the tablets with a full glass of water.

Do not chew the tablets.

When to take it

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

Take this medicine before meals.

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

How long to take it

Quinapril helps control your condition but does not cure it. Therefore, continue taking your medicine for as long as your doctor tells you.

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 missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant. You must

not take quinapril during pregnancy.

- you are breast-feeding or are planning to breast-feed. Do not take quinapril whilst breast-feeding.
- you have experienced excess vomiting or diarrhoea. you may lose too much water and salt and your blood pressure may drop too much.
- you feel light-headed or dizzy after taking your first dose or when your dose is increased.
- you are about to have any blood tests. Quinapril tablets may interfere with the results of some tests.
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

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

If you do not drink enough water while taking quinapril tablets, 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 their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to
- Stop taking your medicine, or change the dosage, without first 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.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking quinapril or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

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

Tell your doctor if you notice any of the following.

Mostly, these are mild:

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

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

These may be serious side effects. You may need medical attention..

- disturbed vision
- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- itchy, raised or red skin rash
- fast or irregular heart beat
- shortness of breath or tightness in the chest
- signs of 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

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

- fainting within a few hours of taking a dose
- 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 the skin
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- chest pain.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay 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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Quinapril 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.

APO-Quinapril 10 mg tablets: Yellow coloured, Capsule shaped, film-coated tablets debossed with '10'

on one side and a break-line on the other side.

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

APO-quinapril is available in blister packs of 30 tablets.

Ingredients

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

It also contains the following inactive ingredients:

- heavy magnesium carbonate
- calcium sulfate dehydrate
- colloidal anhydrous silica
- crospovidone
- povidone
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- talc
- lecithin
- iron oxide yellow
- xanthan gum.

This medicine is gluten-free, lactose-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Quinapril 10 mg tablet:

AUST R 133220.

APO-Quinapril 20 mg tablet:

AUST R 133221

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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