

Quinapril Sandoz®
Quinapril Hydrochloride Tablets
(Quin-A-pril Hi-dro-CLAW-ride)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Quinapril Sandoz. 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 risk of you taking Quinapril Sandoz 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 want to read it again.

WHAT QUINAPRIL SANDOZ IS USED FOR

The name of your medicine is Quinapril Sandoz. It contains the active ingredient quinapril hydrochloride.

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

Hypertension

Quinapril Sandoz 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. 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.

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

Your doctor may have prescribed Quinapril Sandoz for another reason.

How Quinapril Sandoz works

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

It 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.

There is no evidence that this medicine is addictive.

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

BEFORE YOU TAKE QUINAPRIL SANDOZ

When you must not take it

Do not take Quinapril Sandoz if:

- you are allergic to the active ingredient or any of the inactive ingredients mentioned at the end of this leaflet under Product Description.
Symptoms of an allergic reaction to Quinapril Sandoz may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.
- 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 Quinapril Sandoz.
- you 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.
- it is past its expiry date or the packaging appears to have been tampered with
- you are pregnant or intend to become pregnant.
Quinapril Sandoz may enter your womb and affect your baby if you are taking it during pregnancy.
- you are breastfeeding. Quinapril Sandoz may pass into the breast milk and affect your breast-fed baby.

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, especially if they are in the same drug class as quinapril hydrochloride
- any other substances, including 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.

You must also tell your doctor if you:

- have a family history of swelling of the face, lips, tongue, throat, hands or feet
- are following a very low salt diet
- are about to receive desensitisation therapy for an allergy

- are about to have surgery or a general anaesthetic
- are pregnant, breastfeeding or planning to become pregnant.

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

Taking other medicines

Tell your doctor if you are taking any other medicine, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you take any of the following:

- other medicines used to treat high blood pressure
- diuretics, also known as fluid or water tablets
- non-steroidal anti-inflammatory drugs (NSAIDs), 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.

These medicines may be affected by Quinapril Sandoz, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

HOW TO TAKE QUINAPRIL SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

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

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

For high blood pressure

For most patients, not on diuretics, the usual starting dose is 5mg to 10mg 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 10mg and 40mg 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 5mg taken once a day. In most patients, effective doses are between 10mg and 20mg a day. Your doctor will advise whether the dose is to be taken as a single dose or as two separate doses.

Swallow Quinapril Sandoz whole with a full glass of water.

Do not chew the tablets.

Quinapril Sandoz 5mg and 20mg tablets are breakable.
If you need to break Quinapril Sandoz 5mg or 20mg, hold tablet with both hands and snap along break line.

Take Quinapril Sandoz at about the same time each day.

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

Take Quinapril Sandoz before meals.

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

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

Quinapril Sandoz helps control your condition, but does not cure it. Therefore you must take Quinapril Sandoz every day.

If you forget to take your dose

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

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

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

If you take too much

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Quinapril Sandoz.

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

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

WHILE YOU ARE USING QUINAPRIL SANDOZ

Things you must do

- Always follow your doctor's instructions carefully.
- Tell your doctor immediately if you become pregnant or intend to become pregnant while taking Quinapril Sandoz.
- If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Quinapril Sandoz.
- Make sure you drink enough water during exercise and hot weather when you are taking Quinapril Sandoz, especially if you sweat a lot. If you do not drink enough water while taking Quinapril Sandoz, 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.
- If you have excess vomiting or diarrhoea while taking Quinapril Sandoz, tell your doctor. You may lose too much water and salt and your blood pressure may drop too much.
- If you feel light-headed or dizzy after taking your first dose of Quinapril Sandoz, or when your dose is increased, tell your doctor immediately. This is especially important if you are taking Quinapril Sandoz for heart failure.
- If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking Quinapril Sandoz. Your blood pressure may drop suddenly.

- If you are about to have any blood tests, tell your doctor that you are taking Quinapril Sandoz. Quinapril Sandoz may interfere with the results of some tests.
- Have your blood pressure checked when your doctor says, to make sure Quinapril Sandoz 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 stop taking Quinapril Sandoz, or lower the dosage, without your doctor's permission.
- Do not use Quinapril Sandoz to treat any other complaint unless your doctor says so.
- Do not give this medication to anyone else, even if their symptoms seem similar to yours.

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.

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

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

SIDE EFFECTS

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

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

- feeling light-headed, dizzy or faint because your blood pressure is too low
- dry cough
- headache
- feeling sick (nausea) or vomiting
- stomach pain
- diarrhoea
- constipation
- aching, tender or weak muscles not caused by exercise
- unusual tiredness or weakness, fatigue
- feelings of deep sadness and unworthiness (depression)
- difficulty sleeping (insomnia) or strange dreams
- hallucinations
- 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 the more common side effects of Quinapril Sandoz. Mostly, these are mild and short-lived.

Tell your doctor immediately 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
- 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 of Quinapril Sandoz. You may need urgent medical attention. Serious side effects are rare.

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

- swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- fainting within a few hours of taking a dose
- 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.

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

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

Tell your doctor if you notice any other effects.

AFTER USING QUINAPRIL SANDOZ

Storage

Keep Quinapril Sandoz in the original packaging until you need to take it.

Store below 25°C in a dry place, out of the reach of children.

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

Disposal

Return any unused or out of date medicine to your pharmacist.

PRODUCT DESCRIPTION

What Quinapril Sandoz looks like

- Quinapril Sandoz 5mg tablets are beige coloured, oval shaped, scored, film-coated tablets coded "G" on one side and "QP|5" on the other side. Available in blister packs of 30 tablets.

- Quinapril Sandoz 20mg tablets are beige coloured, round, scored, film-coated tablets coded "G" on one side and "QP|20" on the other side. Available in blister packs of 30 tablets.

Ingredients

Active Ingredient

- Each Quinapril Sandoz 5mg tablet contains 5mg quinapril as quinapril hydrochloride.
- Each Quinapril Sandoz 20mg tablet contains 20mg quinapril as quinapril hydrochloride.

Inactive Ingredients

Each Quinapril Sandoz tablet also contains lactose, microcrystalline cellulose, light magnesium oxide, crospovidone, magnesium stearate, titanium dioxide, hypromellose, macrogol 400, polysorbate 80, iron oxide yellow, iron oxide black.

Supplier

Quinapril Sandoz is supplied in Australia by:

Sandoz Pty Ltd

ABN 60 075 449 553
19 Harris Street
Pymont NSW 2009
Australia
Tel: 1800 634 500

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Australian Register Numbers

Quinapril Sandoz 5mg tablets: AUST R 117218
(blisters)

Quinapril Sandoz 20mg tablets: AUST R 117226
(blisters)