

Filpril(R)

Contains the active ingredient quinapril (as hydrochloride)

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Filpril.

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 Filpril 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 Filpril is used for

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

Hypertension

Filpril 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.

How Filpril works

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

Filpril 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.

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

Filpril is not addictive.

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

Before you take Filpril

When you must not take it

Do not take Filpril if you have an allergy to:

- * **any medicine containing quinapril**
- * **any of the ingredients listed at the end of this leaflet**
- * **any other ACE inhibitor.**

Some of the 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.

Do not take Filpril if:

- * **you or your family 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.

Do not take Filpril if you are pregnant or breastfeeding.

Filpril may enter your womb or it may pass into the breast milk and there is the possibility that your baby may be affected. This may occur at any stage of the pregnancy.

Do not take Filpril 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:

- * 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:

- * are following a very low salt diet
- * are about to receive desensitisation therapy for an allergy
- * are about to have low density lipoprotein apheresis treatment (removal of cholesterol from your blood by machine)
- * 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 him/her before you start taking Filpril.

Taking other medicines

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

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

- * other medicines used to treat high blood pressure, e.g. angiotensin receptor blockers
- * 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
- * tetracycline antibiotics
- * certain medicines used to treat bacterial and fungal infections.

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

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

Use in children

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

How to take Filpril

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.

How much to take

For 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 increased 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 Filpril whole with a full glass of water.

Do not chew the tablets.

When to take it

Take Filpril 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 Filpril before meals.

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

How long to take it

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

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine 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 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 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 the nearest hospital, if you think that you or anyone else may have taken too much Filpril. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

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

While you are using Filpril

Things you must do

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Filpril.

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

If you do not drink enough water while taking Filpril, 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 Filpril, 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 Filpril, or when your dose is increased, tell your doctor immediately.

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

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

Your blood pressure may drop suddenly.

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

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

Filpril may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure Filpril 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 give Filpril to anyone else, even if they have the same condition as you.

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

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

Do not take Filpril if you are pregnant, planning to become pregnant or are breast-feeding.

Pregnancy should be excluded before starting treatment with Filpril and avoided during treatment. If a patient needs to become pregnant or pregnancy is detected, Filpril treatment should be stopped immediately and replaced by alternative treatment.

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 Filpril affects you.

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

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.

Side effects

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

Filpril 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.

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

Do not be alarmed by this list.

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 particularly when standing up (this may mean your blood pressure is too low)
- * 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.

These side effects 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
- * 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.

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

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

- * 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
- * symptoms of nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine
- * 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.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

After using Filpril

Storage

Keep your tablets in the box until it is time to take them.

If you take the tablets out of the box they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25 degrees C.

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

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 Filpril 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

Filpril tablets come in three strengths and each has a different appearance:

- * Filpril 5 mg - Reddish-brown, oval, biconvex, film-coated tablet with bisecting score on both sides and debossing "5" on both sides in opposite direction.
- * Filpril 10 mg - Reddish-brown, triangular, biconvex film-coated tablet with bisecting score on both sides and debossing "10" on one side.
- * Filpril 20 mg - Reddish-brown, round, biconvex film-coated tablet, with bisecting score on both sides and debossing "20" on one side.

A box of Filpril contains 30 tablets.

Ingredients

Active ingredient

- * Filpril 5 mg - 5 mg quinapril (as the hydrochloride)
- * Filpril 10 mg - 10 mg quinapril (as the hydrochloride)
- * Filpril 20 mg - 20 mg quinapril (as the hydrochloride)

Other ingredients:

- * magnesium carbonate
- * lactose
- * gelatin
- * crospovidone
- * magnesium stearate
- * candelilla wax
- * iron oxide red
- * titanium dioxide.

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

Supplier

Filpril is supplied in Australia by:
Alphapharm Pty Limited
 (ABN 93 002 359 739)
 Chase Building 2
 Wentworth Park Road
 Glebe NSW 2037
 Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information
 Phone: 1800 028 365

Australian Registration Numbers
 Filpril 5 mg - AUST R 123434
 Filpril 10 mg - AUST R 123435
 Filpril 20 mg - AUST R 123436

This leaflet was prepared on
 28 August 2008.