

ZAPRIL

Cilazapril, tablets, 0.5 mg, 2.5 mg and 5 mg



What is in this leaflet

This leaflet answers some common questions about Zapril.

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 Zapril 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 Zapril is used for

Zapril contains the active ingredient cilazapril. It belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.

Zapril is used to treat

- high blood pressure (hypertension)
- heart failure

High blood pressure (hypertension)

Zapril 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 Zapril works

Zapril 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.

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

Zapril is not addictive.

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

Before you take Zapril

When you must not take it

Do not take Zapril if you have an allergy to:

- **any medicine containing cilazapril, or any other ACE inhibitor medicine.**
- **any of the ingredients listed at the end of this leaflet.** Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, skin rash, itching or hives on the skin, muscle pain or tenderness or joint pain.

Do not take Zapril if you are pregnant. Zapril may affect your developing baby if you take it during pregnancy.

Do not take Zapril if you are breastfeeding. It is possible that Zapril passes into breast milk and therefore there is a possibility that your baby may be affected.

Do not give this medicine to a child. Safety and effectiveness in children have not been established.

Do not take Zapril if you have previously suffered from angioedema (swelling of the skin, particularly of the face and around the lips), when taking other ACE inhibitors.

Do not take Zapril if you are taking sacubitril/valsartan. Taking these medicines together can increase risk of angioedema.

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 Zapril, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as 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
- apheresis (blood is passed through an apparatus that separates out one particular constituent and returns the remainder to the circulation)
- low blood pressure, which you may notice as dizziness or lightheadedness
- diabetes
- high levels of potassium in your blood
- are on a restricted salt diet
- recently suffered from vomiting or diarrhoea
- Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune diseases
- galactose intolerant, or suffer from Lapp lactase deficiency or glucose-galactose malabsorption syndrome
- receiving desensitisation therapy for an allergy.

If you have not told your doctor about any of the above, tell him/her before you start taking Zapril.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

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

- 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, including high dose aspirin
- potassium supplements or potassium-containing salt substitutes, potassium sparing diuretics (e.g. spironolactone, triamterene or amiloride)
- trimethoprim and co-trimoxazole (trimethoprim/sulfamethoxazole) for infections caused by bacteria
- ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection
- heparin, a medicine used to thin blood to prevent clots
- lithium, a medicine used to treat mood swings and some types of depression
- insulin and tablets used to treat diabetes
- general anaesthetics
- tricyclic antidepressants and antipsychotics
- medicines which lower your immune system, such as corticosteroids, cyclosporin or medicines used to treat cancer (including radiation therapy)
- gold compound used to treat rheumatoid arthritis
- desensitisation therapy with bee or wasp venom.

These medicines may be affected by Zapril, 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 have more information on medicines to be careful with or avoid while taking this medicine.

How to take Zapril

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 or bottle, ask your doctor or pharmacist for help.

How much to take

The normal starting dose for **high blood pressure** will be between 0.5 mg and 1.25 mg a day.

If your blood pressure is not adequately controlled by Zapril, your doctor may prescribe a diuretic (water tablet) which will work together with Zapril to better control your blood pressure.

The starting dose for **chronic heart failure** is usually 0.5 mg a day taken together with digitalis and/or diuretics. If you are already taking diuretics, your doctor may also reduce the dose of the diuretics or stop them altogether before you start taking Zapril.

If you have liver or kidney problems your starting dose your starting dose will probably be lower than normal.

If you are elderly you will probably be started on 0.5 mg a day.

In all circumstances where Zapril is prescribed, your doctor may alter your dosage depending upon your individual response to the treatment.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take Zapril 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

It does not matter if you take Zapril before or after food.

How long to take it

Zapril helps control your condition, but does not cure it. Therefore you must take Zapril every day. Continue taking your medicine for as long as your doctor tells you.

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 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 National Poisons Information Centre (0800 POISON or 0800 764 766) 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 Zapril. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Zapril

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist

that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

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

Things you must not do

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

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

Do not stop taking your medicine or lower the dosage without 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.

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

This medicine may cause dizziness, light-headedness and tiredness, in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Things that would be helpful for 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 low-fat diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.
- **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.
- **Exercise** - regular exercise helps to reduce blood pressure and helps get the heart fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is reasonably flat. 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.

Side effects

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

This medicine helps most people with high blood pressure or 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.

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:

Common side effects include:

- feeling light-headed, dizzy or faint
- dry cough
- headache
- unusual tiredness feeling sick (nausea) or vomiting.

Less common side effects include:

- low blood pressure. This may make you feel weak, dizzy or light-headed and may lead to blurred vision and fainting. Excessive lowering of blood pressure may increase the chance of heart attack or stroke in certain patients
- feeling weak
- pains in the chest
- breathing problems, including shortness of breath and tightness in the chest
- a runny or blocked nose and sneezing (rhinitis)
- dry or swollen mouth
- lack of appetite
- change in the way things taste
- diarrhoea and vomiting
- muscle cramps or pain in your muscles or joints
- impotence
- sweating more than usual
- flushing
- sleeping problems.

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

- symptoms of sunburn (such as redness, itching, swelling, blistering) which may occur more quickly than normal
- itchy or raised skin rash, hives or nettlerash
- signs of anaemia such as tiredness, being short of breath and looking pale
- yellowing of the skin and/or eyes
- fast or irregular heart beat
- severe upper stomach pain, often with nausea and vomiting
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers

- bleeding or bruising more easily than normal.

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

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

- severe dizziness and confusion with visual disturbances and speech problems
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- shortness of breath, wheezing or trouble breathing
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks
- chest pain.

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

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.

Some of these side effects (for example, blood pressure, changes in laboratory test findings) can only be found when your doctor does tests from time to time to check your progress.

After using Zapril

Storage

Keep your tablets in the pack or bottle until it is time to take them.

If you take the tablets out of the pack or bottle they may not keep well.

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

Do not store Zapril 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 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 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

ZAPRIL 0.5 mg tablets are white, oval-shaped, biconvex, film coated tablets, with "CI" scoreline "0.5" on one side and "G" on the other side. Zapril 0.5 mg are available in a plastic bottle of 30 and 90 tablets.

ZAPRIL 2.5 mg tablets are pinkish brown, oval-shaped, biconvex, film coated tablets, with "CI" scoreline "2.5" on one side and "G" on the other side. Zapril 2.5 mg are available in a carton of 30 tablets packed in blister strips of 10 tablets per strip or a plastic bottle of 90 tablets.

ZAPRIL 5 mg tablets are reddish brown, oval-shaped, biconvex, film coated tablets, with "CI" scoreline "5" on one side and "G" on the other side. Zapril 5 mg are available in a carton of 30 tablets packed in blister strips of 10 tablets per strip or a plastic bottle of 90 tablets.

The plastic bottles of tablets contain a desiccant and rayon filler (synthetic cotton wool ball). DO NOT EAT either of these items.

Not all presentations may be marketed.

Ingredients

Zapril contains cilazapril as the active ingredient.

Each tablet also contains corn starch, lactose, sodium bicarbonate, colloidal silicon dioxide, sodium stearyl fumarate.

The following colouring agents are also present in the tablets:

- titanium dioxide
- triacetin
- hypromellose (0.5 mg)
- red iron oxide (2.5 mg)
- yellow iron oxide (2.5 mg)
- hydroxypropylmethylcellulose (2.5 mg, 5 mg)
- polydextrose (2.5 mg, 5 mg)
- macrogol (2.5 mg, 5 mg)
- sunset yellow (5 mg)
- indigo carmine aluminium lake blue (5 mg)
- D&C Yellow 10 (5 mg)
- FD&C Red 40 (5 mg).

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

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:
Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.
Telephone: (09) 579 2792

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