

[Medicine name][®] *(if phonetic spelling is required, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).*

Generic name

Consumer Medicine Information

Consumer Name
 Consumer Address
 Consumer Address

Date of Dispensing

*Pharmacist Name
 Pharmacist Address
 Pharmacist Address*

What is in this leaflet¹

This leaflet answers some common questions about [Medicine name].

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist².

All medicines have risks and benefits. Your doctor has weighed the risks of you taking [Medicine name] 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.

Note: The statements in this core document are optional. Some may not be appropriate for a given product. In order to achieve consistency, however, CMI writers are encouraged to use these statements and follow the Second Edition of the Usability Guidelines wherever possible.

¹ Depending on the length of your CMI, consider using a table of contents (see Second Edition of the Usability Guidelines).

² The reference to pharmacists may be especially relevant for S3 medicines.

What [Medicine name] is used for

Include information on the expected effects of using [Medicine name], the therapeutic indications (that is, what it is used for), the pharmacotherapeutic group and how it works etc.

[Medicine name] belongs to a group of medicines called angiotensin converting enzyme (ACE) inhibitors.³

[Medicine name] is used to treat⁴:

- high blood pressure (hypertension)
- heart failure
- patients who have had a heart attack
- kidney problems in some patients who have Type I or insulin-dependent diabetes

Hypertension

[Medicine name] 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

³ *As this doesn't directly answer the question "What [Medicine name] is used for", consider placing this statement towards the end of this section.*

⁴ *Consider writing this in sentence format ("[Medicine name] is used to lower high blood pressure (hypertension). It is also used to treat heart failure etc.")*

(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.

Heart Attack

A heart attack occurs when one of the major blood vessels supplying blood to your heart becomes blocked. This means that your heart can not receive the oxygen it needs and becomes damaged. This may lead to further problems, such as heart failure, irregular heart rhythms and blood clots.

Core CMI for the ACE Inhibitors (*text in italics is instructional for the CMI writer only*)**Kidney Problems in Type I Diabetes**

If you have Type I or insulin-dependent diabetes, you may develop kidney problems. The problems do not start at the same time as your diabetes is discovered; kidney problems develop slowly over several years. Good control of your blood sugar and blood pressure are important in keeping your kidneys healthy, but may not always prevent kidney damage from occurring.

How [Medicine name] works

[Medicine name] works by widening your blood vessels, which reduces pressure in the vessels, making it easier for your heart to pump blood around your body (*indication = hypertension*). 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. (*indication = heart failure*)

By increasing the supply of oxygen to your heart, your heart does not have to work as hard which may reduce the risk of further damage to your heart after you have had a heart attack. (*indication = patients who have had a heart attack*)

By reducing blood pressure, [Medicine name] may also slow down the kidney damage caused by type 1 insulin-dependent diabetes. (*indication = diabetic nephropathy*)

Your doctor may have prescribed [Medicine name] for another reason. Ask your doctor if you have any questions about why [Medicine name] has been prescribed for you.

[Medicine name] is not addictive.

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

Use in children

The safety and effectiveness of [Medicine name] in children have not been established.

Before you take [Medicine name]**When you must not take it**

Alternatives:

Do not take [Medicine name] if:

- **you have an allergy to [Medicine name] or any other medicine containing (active ingredient), or any of the ingredients listed at the end of this leaflet.**
Symptoms of an allergic reaction to [Medicine name] may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain (*as per PI*).
- **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 (as per PI).**
If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to [Medicine name].
- **you have a history of swelling of the face, lips, tongue, throat, hands or feet (as per PI), for no apparent reason. (idiopathic angioedema)**

Do not take [Medicine name] if you are pregnant.

[Medicine name] may affect your developing baby if you take it during pregnancy.

Do not take [Medicine name] if you are breastfeeding.

[Medicine name] passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

Any other contraindications as per PI.

Do not take [Medicine name] after the expiry date (EXP)⁵ printed on the pack.

Do not take [Medicine name] 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 [Medicine name], 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 (*impaired renal function, dialysis, bilateral or unilateral renal stenosis*)
- liver problems (*impaired hepatic function*)
- heart problems (*aortic stenosis, valvular stenosis, hypertrophic cardiomyopathy*)
- low blood pressure, which you may notice as dizziness or lightheadedness (*hypotension*)
- diabetes (*diabetes*)
- high levels of potassium in your blood (*hyperkalaemia*)
- Systemic Lupus Erythematosus (SLE), scleroderma or other autoimmune diseases (*SLE, scleroderma, connective tissue disease, collagen vascular disease*)
- *List any other medical conditions which are precautions, as per PI*

Tell your doctor if you have a family history of swelling of the

⁵ Only include 'EXP' if that is the abbreviation used on your packaging.

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face, lips, tongue, throat, hands or feet (as per PI). (*hereditary angioedema*)

Tell your doctor if you are following a very low salt diet.

Tell your doctor if you are about to receive desensitisation therapy for an allergy.

Tell your doctor if you plan to become pregnant or breastfeed.

Any other precautions, as per PI.

If you have not told your doctor about any of the above, tell them before you start taking [Medicine name].

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 [Medicine name] 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
- potassium supplements or potassium-containing salt substitutes
- lithium, a medicine used to treat mood swings and some types of depression
- insulin and tablets used to treat diabetes
- tetracycline antibiotics
- antacids, medicines used to treat heartburn and indigestion
- some medicines used to control your appetite
- some medicines which are used to treat coughs, colds, hayfever or sinus problems
- general anaesthetics
- medicines which lower your immune system, such as corticosteroids, cyclosporin or

medicines used to treat cancer (including radiation therapy)

- *List any other potential drug interactions, as per PI*

These medicines may be affected by [Medicine name], 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 [Medicine name].

How to take [Medicine name]

This information will be product specific, consistent with the approved PI. The following subheadings and order of information is suggested, but will depend upon the particular product and the amount of information to be given.

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/capsules 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/bottle, ask your doctor or pharmacist for help.

How much to take

Include dosage ranges, usual doses for each indication or patient group etc.

How to take it

Include any special precautions etc.

Swallow [Medicine name] whole with a full glass of water.

or:

Shake the bottle well and accurately measure the dose with a medicine measure.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

When to take it

Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary. Include time to take medicine with respect to food, dosing intervals, etc.

Take [Medicine name] at about the same time each day.

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

It does not matter if you take [Medicine name] before or after food.

Take [Medicine name] on an empty stomach, for example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of [Medicine name].

If you need to take an antacid, take it at least 2 hours before or 2 hours after your dose of [Medicine name].

How long to take it

Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

[Medicine name] helps control your condition, but does not cure it. Therefore you must take [Medicine name] 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

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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)⁶, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention⁷.

If you take too much [Medicine name], you may feel light-headed, dizzy or you may faint. (*or other symptoms in PI*)

While you are using [Medicine name]

Things you must do

Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

Tell any other doctors, dentists, and pharmacists who are

⁶ Consider including the relevant New Zealand telephone numbers here.

⁷ The reference to accident and emergency and urgent medical attention could be left out, depending on the type of product.

[Medicine name]

treating you that you are taking [Medicine name].

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

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

If you do not drink enough water while taking [Medicine Name], 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 [Medicine name], 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 [Medicine name], or when your dose is increased, tell your doctor immediately.

This is especially important if you are taking [Medicine name] for heart failure.

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

Your blood pressure may drop suddenly.

If you become pregnant while taking [Medicine name], tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking [Medicine name].

[Medicine name] may interfere with the results of some tests.

Have your blood pressure checked when your doctor says, to make sure [Medicine name] 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.

Any other instructions, as per PI.

Things you must not do

Do not give [Medicine name] to anyone else, even if they have the same condition as you.

Do not take [Medicine name] to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking [Medicine name], or lower the dosage, without checking with your doctor.

Any other instructions, as per PI.

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 [Medicine name] affects you.

As with other ACE inhibitor medicines, [Medicine name] may cause dizziness, light-headedness, tiredness, drowsiness (*as per PI*) in some people. Make sure you know how you react to [Medicine name] 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.

Any other instructions, as per PI.

Things that would be helpful for your blood pressure or heart failure⁸

⁸ This section is optional. You may like to include it, leave it out, or include a similar, shorter section.

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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

The side effects for a particular product will depend on the PI and the company's disclosure policy.

The following side effects have been listed according to severity. Select those side effects applicable to your product.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking [Medicine name].

[Medicine name] helps most people with *indication*, 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 treatment 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.⁹

Ask your doctor or pharmacist to answer any questions you may have.

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.¹⁰

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

- feeling light-headed, dizzy or faint (*dizziness, light-headedness, (orthostatic hypotension)*)
- dry cough
- headache
- feeling sick (nausea) or vomiting
- loss of appetite (*anorexia*)
- stomach pain
- diarrhoea
- constipation
- aching, tender or weak muscles not caused by exercise (*myalgia*)
- muscle cramps
- pain in the joints (*arthralgia*)
- unusual tiredness or weakness, fatigue (*fatigue*)
- difficulty sleeping (insomnia) or strange dreams
- feelings of deep sadness and unworthiness (depression) (*depression*)
- loss of sexual drive (*loss of libido*)
- difficulty in getting or maintaining an erection (impotence) (*impotence*)
- ringing or buzzing in the ears (*tinnitus*)
- hair loss or thinning (*alopecia*)

⁹ Some medicines might need the preceding statement concerning the increased risk of side effects in the elderly.

¹⁰ This paragraph may be moved to the end of the section ("Do not be alarmed by this list of side effects. You may not experience any of them.")

- dry or itchy eyes
- runny or blocked nose, or sneezing (*rhinitis*)
- facial pressure or pain (*sinus pain*)
- dry mouth
- taste disturbances or loss of taste (*dysgeusia*)
- mouth or tongue ulcers
- flushed or pale skin (*flushing, pallor, anaemia (with other side effects already listed eg dizziness and headaches)*)
- fever
- confusion or nervousness (*hyperkalaemia*)¹¹
- *list any other mild side effects, as per PI*¹²

These side effects are usually mild.

or:

These are the more common side effects of [Medicine name]. (Mostly these are mild and short-lived.)

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 (*photosensitivity*)
- itchy or raised skin rash, hives or nettle rash (*rash, urticaria, maculopapular rash, pruritic rash*)
- signs of anaemia such as tiredness, being short of breath and looking pale¹³ (*anaemia*)
- yellowing of the skin and/or eyes (*jaundice, cholestasis*)
- swollen glands in the neck, armpit or groin (*lymphadenopathy*)

¹¹ Other symptoms of hyperkalaemia are already included in the side effects list.

¹² List medical terms in brackets after the consumer terminology. The medical terms are not to go into the CMI; rather, they are there to help the CMI writer choose applicable wording for adverse events listed in their PI.

¹³ Be careful not to confuse the consumer if these symptoms are present elsewhere in your side effects lists.

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- breast enlargement in men (*gynaecomastia*)
- fast or irregular heart beat (*tachycardia, palpitations, rhythmic disturbances*)
- shortness of breath or tightness in the chest (*dyspnoea, SOB, chest tightness*)
- tingling or numbness in the hands, feet or ankles (*paraesthesia*)
- numbness, tingling and colour change (white, blue then red) in the fingers or toes when exposed to the cold (*Raynaud's syndrome*)
- severe upper stomach pain, often with nausea and vomiting (*pancreatitis*)
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers (*agranulocytosis, neutropenia, leucopenia*)
- passing little or no urine (*renal insufficiency, acute renal failure, oligouria*)
- passing more urine than is normal for you (*polyuria*)
- swelling of the hands, feet or ankles (*peripheral oedema*)
- bleeding or bruising more easily than normal (*thrombocytopenia, pancytopenia*)
- *list any other serious side effects, as per PI*

These may be serious side effects. You may need medical attention. Serious side effects are rare.

If any of the following happen, stop taking [Medicine name] and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- fainting within a few hours of taking a dose (*syncope*)
- severe dizziness and confusion with visual disturbances and speech problems (*stroke*)
- collapse, numbness or weakness in the arms or legs (*collapse, asthenia*)
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (*angioedema*)

- wheezing or difficulty breathing (*wheezing, asthma*)
- pink or red itchy spots on the skin which may blister and progress to form raised, red, pale-centred marks (*erythema multiforme, bullous pemphigous, lichenoid eruption*)
- severe flaking or peeling of the skin (*exfoliative dermatitis*)
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals (*Steven Johnson Syndrome*)
- chest pain (*cardiac arrest, myocardial infarction, angina*)
- *list any other life threatening side effects, as per PI*

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

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

After using [Medicine name]

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

Storage

Keep your tablets/capsules/ syrup in the pack/bottle until it is time to take them.

If you take the tablets/capsules/ suppositories/eyedrops/ointment etc. out of the pack/bottle they will not keep well.

Keep your tablets/capsules/ syrup in a cool dry place where the temperature stays below x°C.

Do not store [Medicine name] 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.

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 [Medicine name] or the tablets/capsules/ syrup has/have passed its/their expiry date, ask your pharmacist what to do with any that is/are left over.

Product description

This information will be product specific. Following are some examples from the Usability Guidelines. Choose whichever is appropriate or amend as necessary.

What it looks like

Include any tablet scoring etc.

Ingredients

Active ingredients:

- *list actives*
- Other ingredients

- *list excipients*

If appropriate:

[Medicine name] does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Where Australian Food Standard codes exist, these could follow each Australian Approved name.

Manufacturer/Distributor/Supplier

Include:

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- *Name and address of sponsor*
- *AUST R number*
- *Date of preparation*