

[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 pharmacist.

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.

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. Consider using dot points to separate the indications, especially if your drug is used to treat several conditions.

[Medicine name] is a fluid tablet or diuretic. It helps reduce the amount of excess fluid in the body by increasing the amount of urine produced.

It is used to treat swelling of the ankles, feet or legs, which is called oedema. This can occur in some heart, lung or kidney conditions (*other indications, as per PI*).

[Medicine name] may also be used to treat fluid build-up during premenstrual tension (PMT).

[Medicine name] may also be used to lower high blood pressure (which is also called hypertension).

[Medicine name] may be taken alone or in combination with other medicines to treat your condition.

When taken with other diuretics, [Medicine name] helps reduce the amount of fluid in your body while at the same time helping to maintain normal levels of potassium in your blood. This is because many other diuretics may lead to low levels of potassium.

Non-approved uses:

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.

Statement about addictive properties:

[Medicine name] is not addictive.

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

Use in children statement²:

[Medicine name] is not recommended for use in children (under the age of x), as there have been no/not enough studies of its effects in children.

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

For potassium-sparing diuretics:

² Consider this position if use in children is not a contraindication. Will need to test to determine the most appropriate location.

**Before you take
[Medicine name]**

or

**Before you are given
[Medicine name]**

***When you must not take it
When you must not be
given it***

(as per PI):

**Do not take [Medicine name] if
you have an allergy to:**

- [Medicine name] or any of the ingredients listed at the end of this leaflet.
- medicines which contain sulfur, such as sulfur antibiotics or some medicines used to treat diabetes. (examples can be given, with trade mark symbol at first occurrence, if this is company policy)

Symptoms of an allergic reaction may include: (list hypersensitivity/allergic symptoms from your PI)³

**If you are not sure if you have an
allergy to [Medicine name] or
medicines which contain sulfur,
check with your doctor.****Do not take [Medicine name] if
you have any of the following
medical conditions:**

- certain kidney problems (acute renal insufficiency)⁴
- no production or passing of urine (anuria)
- low blood pressure (hypotension)
- high sodium levels in your blood (hypernatraemia)

³ Do not include allergy symptoms if they are not listed in your PI.

⁴ The medical terms listed in brackets after the consumer terminology are not to go into the CMI; rather, they are there to help the CMI writer choose applicable wording for medical conditions listed in the contraindications section of their PI. Only list those conditions applicable to your product.

- high potassium levels in your blood (hyperkalaemia)
- very low blood pressure (hypovolaemia)
- coma (hepatic coma)
- any others, as per PI

If pregnancy a contraindication:

**Do not take [Medicine name] if
you are pregnant or intend to
become pregnant.**

Like most diuretic medicines, [Medicine name] is not recommended for use during pregnancy.

Alternative explanation:

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

If breastfeeding a contraindication:

**Do not take [Medicine name] if
you are breast-feeding or plan to
breast-feed.**

Like most diuretic medicines, [Medicine name] is not recommended while you are breast-feeding.

Alternative explanations:

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

It is not known whether [Medicine name] passes into breast milk.

Any other contraindications as per PI.

If use in children a contraindication:

**Do not give [Medicine name] to a
child (under x years).**

The safety and effectiveness of [Medicine name] in children (under x years) have not been established.

Alternative explanations:

There is no/not enough experience with the use of [Medicine name] in children.

[Medicine name] is not recommended for use in children (under x years).

**Do not give [Medicine name] to
newborn babies who have liver
problems, such as jaundice.**
Symptoms of jaundice include
yellowing of the skin and/or eyes.

Tampering and expiry date
warnings:

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

If you take this medicine after the expiry date has passed, it may not work (as well).

**Do not take [Medicine name] if
the packaging is torn or shows
signs of tampering.**

**If you are not sure whether you
should start taking [Medicine
name], talk to your doctor.**

***Before you start to take it
Before you are given 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 are
pregnant or intend to become
pregnant.**

Your doctor will discuss the possible risks and benefits of using [Medicine name] during pregnancy.

Alternative explanation:

Like most diuretic medicines, [Medicine name] is not recommended for use during pregnancy. If there is a need to consider [Medicine name] during your pregnancy, your doctor will discuss with you the benefits and risks of taking it.

**Tell your doctor if you are
breast-feeding or plan to breast-
feed.**

Your doctor will discuss the possible risks and benefits of taking [Medicine name] during breastfeeding.

Alternative explanation:

It is not known whether [Medicine name] passes into breast milk. If there is a need to consider [Medicine name] while you are breast-feeding, your doctor will discuss with you the benefits and risks of taking it.

Tell your doctor if you have or have had any medical conditions, especially the following:

- liver problems (*impaired hepatic function, borderline hepatic insufficiency, progressive liver disease, decompensating cirrhosis*)
- kidney problems (*azotaemia, renal insufficiency*)
- heart and lung problems (*cardiopulmonary disease*)
- high cholesterol levels (*hypercholesterolaemia*)
- asthma (*asthma*)
- diabetes (*diabetes*)
- gout (*gout*)
- passing less urine than is normal for you (*impairment of micturition*)
- difficulty passing urine (*oliguria*)
- no production or passing of urine (*anuria*)
- prostate problems
- Systemic Lupus Erythematosus (SLE), a disease affecting the skin, joints and kidneys (*SLE*)
- *any others, 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 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 should not be taken with [Medicine name]. This includes large amounts of laxatives.

Some medicines and [Medicine name] may interfere with each other. These include:

- certain other fluid tablets or diuretic medicines
- medicines used to treat high blood pressure and some other heart conditions
- digoxin, a medicine used to treat heart failure
- non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis
- tablets, preparations or supplements which contain potassium
- medicines used to relax muscles before or during surgery
- steroid medicines such as cortisone, prednisone and dexamethasone
- lithium, a medicine used to treat mood swings and some types of depression
- medicines used in emergency situations such as adrenaline and noradrenaline
- cisplatin, a medicine used to treat cancer
- theophylline, a medicine used to treat asthma
- aminoglycoside antibiotics, including gentamicin
- amphotericin, a medicine used to treat fungal infections
- carbenoxolone, a medicine used to treat mouth ulcers
- barbiturates, medicines used to treat epilepsy, to produce calmness or to help you sleep
- narcotic/strong pain killers, such as codeine, morphine and dextropropoxyphene
- insulin and tablets used to treat diabetes
- cholestyramine and colestipol, medicines used to treat high blood cholesterol levels
- *any others, as per PI*
- alcohol

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 or pharmacist 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 order of information is suggested, but will depend upon the particular product and the amount of information. These subheadings and information are suggested but may not be necessary in all cases.

Take [Medicine name] only when prescribed by your doctor.

For oral medicines:

How much to take

Include dosage ranges, usual doses for each indication or patient group, or a general statement that the dose will depend on the patient and will be determined by the doctor or pharmacist.

Your doctor 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.

Include adult dosage range, children dosage range etc. here

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

They may differ from the information contained in this leaflet.

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

How to take it

Including taking with water or any other special precautions, if appropriate.

Some examples from the Second Edition of the Usability Guidelines:

Swallow [Medicine name] with a glass of water.

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

When to take it

Include time with respect to food, dosing intervals, etc.

Take [Medicine name] at about the same time each day unless your doctor tells you otherwise. 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.

If you are taking [Medicine name] once a day, this is best in the morning, for example, at breakfast time (if appropriate).

If you are taking [Medicine name] more than once a day, take your first dose immediately after breakfast and take your last dose no later than 6pm, unless your doctor tells you otherwise. [Medicine name] may increase the amount of urine you pass and also the number of times you need to go to the toilet. By taking your last dose no later than 6pm, there may be less chance that your sleep is disturbed.

Alternative instruction:

Take [Medicine name] during or immediately after a meal, at about the same time each day. If you take [Medicine name] on an empty stomach, it may cause stomach upset.

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

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.⁵

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 appropriate).

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.

How long to take it

Oedema:

[Medicine name] helps control your condition and lower the fluid build-up in your body. Continue taking the tablets for as long as your doctor tells you.

[Medicine name] (also) helps lower the build-up of fluid in your body which can occur before the start of your menstrual period. Therefore you should take [Medicine name] from the start of your symptoms/for x days before the start of your menstrual period (choose whichever is applicable) until the onset of your period.

Hypertension:

[Medicine name] helps control your blood pressure, but does not cure it. Continue taking the tablets for as long as your doctor tells you.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26)⁶, or go to

⁵ Consider inserting a timeframe informing consumers when it would be appropriate to take the missed dose, and when it would be better to skip the dose.

⁶ Consider including the relevant New Zealand telephone numbers here.

Accident and Emergency at your 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 (list symptoms in Pl)

For injections:

How [Medicine name] is given

Include dosage ranges, usual doses for each indication or patient group, or a general statement that the dose will depend on the patient and will be determined by the doctor.

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight.

How it is given

[Medicine name] is given as an injection into a muscle or as a slow injection into a vein. [Medicine name] must only be given by a doctor or nurse.

If you are given too much (overdose)

Your doctor or pharmacist has information on how to recognise and treat an overdose. Ask your doctor or pharmacist if you have any concerns.

While you are using [Medicine name]

Things you must do

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

Precautions or warnings as per PI.

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

Tell your doctor if you have excessive vomiting or diarrhoea or experience any of the following symptoms:

- dry mouth or thirst
- weakness, tiredness or drowsiness
- muscle pain or cramps
- fast heart beat
- passing less urine than normal

If you experience these symptoms, you may be dehydrated because you are losing too much water.

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 or light-headed or sick. This is because your blood pressure is dropping suddenly and you are dehydrating. If you continue to feel unwell, tell your doctor.

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 these tests.

For hypertensive indications:

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

For potassium-sparing diuretics:

Talk to your doctor about foods or drinks which have a high potassium content.

[Medicine name] helps to maintain normal potassium levels in your body. However, if you eat foods or have drinks that are high in potassium, the levels of potassium in your blood may increase. Too much potassium can be harmful.

[Medicine name]

For all products:

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

Your blood pressure may drop suddenly.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking/being given [Medicine name].

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

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 tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how [Medicine name] affects you.

As with other diuretic medicines, [Medicine name] may cause dizziness or light-headedness (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 or take strong pain killers, dizziness or light-headedness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy when you begin to take/after you are given Medicine Name. This is because your blood pressure is falling suddenly. 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 gets worse or continues, talk to your doctor.**

Any other precautions as per PI.

Side effects

The side effects for a particular product will depend on the Product Information 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, 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.

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:

- ringing or buzzing in the ears (*tinnitus*)
- very dry mouth or unusual thirst (*dry mouth, thirst*)
- weakness or tiredness (*fatigue*)
- numbness or tingling in the hands and/or feet (*paraesthesia*)
- muscle pains or cramps (*muscle cramps*)
- restlessness (*restlessness*)
- drowsiness or a lack of energy (*drowsiness, lethargy*)

- dizziness or lightheadedness (*dizziness, lightheadedness, orthostatic hypotension*)
- unsteadiness when walking (*ataxia*)
- headache (*headache*)
- fever (*fever*)
- vomiting or nausea (*vomiting, nausea*)
- stomach pain and discomfort (*peptic ulceration*)
- stomach cramps, diarrhoea or constipation (*stomach cramps, diarrhoea, constipation*)
- loss of control of your bladder or bowels (incontinence) (*incontinence*)
- blurred vision (*blurred vision*)
- unusual bleeding or bruising under the skin (*purpura*)
- if female, changes in your menstrual periods (*irregular menses, amenorrhoea, post-menopausal bleeding*)
- if male, inability to get or maintain an erection (*impotence*)
- breast enlargement in men (*gynecomastia*)
- *any others, as per PI*

These side effects are usually mild.

Alternative explanations:

These are the more common side effects of [Medicine name].

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

Tell your doctor or pharmacist immediately if you notice any of the following:

- irregular or fast heart beat (*tachycardia, arrhythmia*)
- passing less urine than is normal for you (*impairment of micturition*)
- pain when passing urine (*dysuria*)
- yellowing of the skin and/or eyes, also called jaundice (*jaundice*)
- skin rash, itchiness (*skin rash, pruritis*)
- severe stomach pain, often with nausea or vomiting (*gastritis, pancreatitis*)

- severe dizziness or a spinning sensation (*vertigo*)
- confusion (*confusion*)
- lumps in your breast (*breast cancer*)
- increased sensitivity to sunlight caused by some medicines (*photosensitive dermatitis*)
- flaking or peeling of the skin (*exfoliative dermatitis*)
- signs of anaemia such as tiredness, being short of breath when exercising, dizziness and looking pale (*anaemia*)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers (*leukopenia, agranulocytosis, neutropenia*)
- bleeding or bruising more easily than normal, nose bleeds (*thrombocytopenia*)
- signs of gout such as painful, swollen joints (*gout*)
- *any others, as per PI*

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

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

- sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (*anaphylaxis*)
- severe skin reaction starting with painful red areas, then large blisters and ending with peeling of layers of skin. This may be accompanied by fever and chills, aching muscles and generally feeling unwell (*toxic epidermal necrolysis*)
- pinkish, itchy swellings on the skin, also called hives or nettle rash (*urticaria*)
- red, often itchy spots, similar to the rash of measles, which starts on the limbs and sometimes on the face and the rest of the body. The spots may blister or may progress to form raised, red, pale-centred marks. Those affected may have fever, sore

- throat, headache and/or diarrhoea (*erythema multiforme*)
- chest pain (*ischemia, angina pectoris*)
- fainting (*hypovolemia*)
- fast, weak pulse (*hypovolemia*)
- fits or seizures (*convulsions*)
- vomiting blood or material that looks like coffee grounds, bleeding from the back passage, black sticky bowel motions (stools) or bloody diarrhoea (*gastric hemorrhage*)
- lockjaw (*tetany*)
- loss of hearing (*reversible or permanent deafness*)
- *list as per PI*

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

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.⁸

After using [Medicine name]

This information will be product specific. See general statements in Second Edition of the Usability Guidelines, including:

Storage

⁸ Consider placing this statement at the beginning of this section.

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

If you take the tablets or solution out of the pack/bottle they will not keep well.

Keep your tablets or solution in a cool dry place away from light 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 in the car on hot days or on window sills.

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.

Injections only:

Storage

[Medicine name] will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below x°C.

Disposal

If your doctor or pharmacist tells you to stop taking [Medicine name] or the tablets or solution has/have passed their expiry date, ask your pharmacist what to do with any that are left over.

Active ingredients:

- *list actives*

Other ingredients:

- *list excipients*

[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:

- *Name and address of sponsor*
- *ARTG number*
- *Date of preparation*

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.

Product description

This information will be product specific. The Second Edition of the Usability Guidelines suggest the following order:

What it looks like

Ingredients

[Medicine name]