

[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 or pharmacist 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 taking [Medicine name], the therapeutic indications (that is, what it is taken for), the pharmacotherapeutic group and how it works etc.

[Medicine name] is used to relieve or prevent runny nose, sneezing and watering, itchy or red eyes caused by allergies, such as to pollen (hay fever) or house dust mites. It is also used to treat itchy rashes, hives, dermatitis, eczema and mild reactions to insect bites.

[Medicine name] may also be used in the treatment and prevention of inner ear disorders, motion sickness, nausea, vomiting and dizziness.

If a sedating antihistamine:

[Medicine name] may also be used to help control anxiety or help you go to sleep.

For pre-medication use:

[Medicine name] may be given to you by injection before an operation to help you go to sleep.

[Medicine name] belongs to a group of medicines called antihistamines. It works by blocking the action of histamine and other substances produced by the body, which are causing your allergies or itchiness.

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.

Alternative explanation:

There is no evidence that [Medicine name] is addictive.

If a prescription-only medicine:

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

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.

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.

Symptoms of an allergic reaction to [Medicine name] may include³ ... (list allergic symptoms as in 'side effects' section of PI)

Do not take [Medicine name] if you have, or have had, any of the following medical conditions:

- asthma
- severe liver or kidney disease
- closed-angle glaucoma
- unusual heart beats
- prostate problems
- difficulty passing urine
- a narrowing or blockage between the stomach and small intestine which causes vomiting of undigested food
- any others, as per PI

Do not take [Medicine name] if you are taking or being given any of the following medicines:

- itraconazole, ketoconazole or miconazole, medicines used to treat fungal infections
- erythromycin, josamycin or roxithromycin, medicines used to treat bacterial infections
- quinine, a medicine used to treat muscle cramps or prevent malaria
- medicines used to treat unusual heart beats
- monoamine oxidase inhibitor (MAOI) medicines, including moclobemide, phenelzine and tranylcypromine, which are used to treat depression
- any other contraindicated medicines, as per PI

If pregnancy a contraindication:

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

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

Alternative explanation:

³ Consider whether it is appropriate to include these symptoms, in view of the indications.

[Medicine name]

[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 antihistamine 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/infants/newborn babies, unless directed by the child's doctor or pharmacist.

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.

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], contact your doctor or pharmacist.

**Before you start to take it⁴
Before you are given it**

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

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

Alternative explanations:

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

Like most antihistamine medicines, [Medicine name] is not recommended during pregnancy.

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

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

Alternative explanations:

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

Like most antihistamine medicines, [Medicine name] is not recommended while you are breast-feeding. If there is a need to consider [Medicine name] while

⁴ Depending on the product and its Scheduling (S3 or S4), it may be more appropriate to refer to either the doctor or the pharmacist in the following paragraphs, not both.

you are breast-feeding, your doctor or pharmacist will discuss with you the benefits and risks of taking it.

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

- epilepsy
- liver or kidney disease
- breathing problems, including asthma or bronchitis
- an overactive thyroid gland
- heart disease
- high blood pressure
- prostate problems
- raised pressure in the eye
- *any others, as per PI*

If you have not told your doctor or pharmacist 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 should not be taken with [Medicine name]. These include:

- itraconazole, ketoconazole or miconazole, medicines used to treat fungal infections
- erythromycin, josamycin or roxithromycin, medicines used to treat bacterial infections
- quinine, a medicine used to treat muscle cramps or prevent malaria
- medicines used to treat unusual heart beats
- monoamine oxidase inhibitor (MAOI) medicines, including moclobemide, phenelzine and tranylcypromine, which are used to treat depression
- *any other contraindicated medicines, as per PI*

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

- alcohol

[Medicine name]

- tricyclic antidepressants, medicines used to treat depression
- strong / narcotic pain killers, such as codeine, morphine and dextropropoxyphene
- some medicines used for sedation or to help you sleep
- some medicines used to treat anxiety
- some medicines used to stop blood clotting, such as warfarin
- *any others, 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 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.

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 or pharmacist will tell you how many tablets/capsules you will need to take each day.

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/bottle, ask your doctor or pharmacist for help.

How to take it

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

Swallow [Medicine name] with a glass of water.

When to take it

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

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

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

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

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 you missed.

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

Include any relevant information, depending on the PI.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26)⁵, or go to 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 attention⁶.

If you take too much [Medicine name], you may feel:

- (list overdose symptoms in PI)

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.

How it is given

[Medicine name] is given as an injection into a muscle or as a slow injection into a vein. [Medicine name] should only be given by a doctor, nurse or other trained person.

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

Precautions or warnings as per PI.

Tell any other doctors, dentists, and pharmacists who are 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].

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

Alternative instruction if pregnancy a contraindication:

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

For sedating antihistamines with a hypnotic indication:

If sleeplessness (insomnia) persists for more than x nights, tell your doctor.

Insomnia might be a sign of another medical problem.

Things you must not do

For prescription antihistamines:

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

For prescription and OTC antihistamines:

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

For sedating antihistamines:

If you feel tired, drowsy, dizzy or light-headed, do not drive or operate machinery.

As with some other antihistamine medicines, [Medicine name] may cause tiredness, drowsiness, dizziness or light-headedness (as per PI) in some people. If you drink alcohol, drowsiness, dizziness or light-headedness may be worse.

Things to be careful of

For non-sedating antihistamines:

Make sure you know how you react to [Medicine name] before you drive, operate machinery, or do anything else that could be dangerous if you are tired, drowsy, dizzy or light-headed (as per PI).

[Medicine name] is unlikely to make you drowsy. However, if you are drowsy, do not drive a car or operate machinery.

If alcohol a precaution:

Be careful drinking alcohol while taking [Medicine name].

The effects of alcohol can be increased by some antihistamine medicines, including [Medicine name].

Alternative statement:

Avoid drinking alcohol while taking [Medicine name].

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

⁵ Consider including the relevant New Zealand telephone numbers here.

⁶ The reference to accident and emergency and urgent medical attention could be left out, depending on the type of product.

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.⁷

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:

- nervousness (*nervousness*)⁸
- confusion (*confusion*)
- mood changes
- irritability (*irritability*)
- excitation (*excitation*)
- restlessness (*restlessness*)
- lack of concentration
- a lack of or disturbed coordination (*incoordination, disturbed coordination*)
- drowsiness (*sedation*)
- dizziness (*dizziness*)
- buzzing or ringing in the ears (*tinnitus*)
- nausea and/or vomiting (*nausea, vomiting*)
- upset stomach (*epigastric distress*)
- dry mouth, nose and/or throat
- sleepiness (*somnolence*)
- tiredness (*lassitude*)
- fatigue (*fatigue*)
- inability to sleep (*insomnia*)
- nightmares
- headache (*headache*)
- blurred vision (*blurred vision*)
- loss of appetite (*anorexia*)
- increased appetite
- weight gain
- diarrhoea (*diarrhoea*)
- constipation (*constipation*)
- muscle or joint pain
- muscle weakness

⁷ Some medicines might need the preceding statement concerning the increased risk of side effects in the elderly.

⁸ 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 adverse events listed in their PI.

- unusual movements, including tremor (*tremor*)
- excessive sweating (*perspiration*)
- swelling of hands, feet and/or ankles (*peripheral oedema*)
- 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 immediately if you notice any of the following:

- wheezing or being short of breath
- fast, pounding or irregular heart beats (*arrhythmia, palpitations, tachycardia*)
- slow heart beat (*bradycardia*)
- skin rash (*rash*)
- pinkish, itchy swellings on the skin, also called hives or nettle rash (*urticaria*)
- frequent infections such as fever, severe chills, sore throat or mouth ulcers (*agranulocytosis, leukopenia*)
- tiredness, headache, being short of breath when exercising, dizziness, looking pale and yellowing of the skin and/or eyes (*haemolytic anaemia*)
- yellowing of the skin and/or eyes (*jaundice*)
- unable to pass urine (*urinary retention*)
- difficulty passing urine (*difficult micturition*)
- passing urine more often than usual (*frequent micturition*)
- seeing, feeling or hearing things that are not there (*hallucinations*)
- spinning sensation (*vertigo*)
- fainting
- unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs (*extrapyramidal symptoms*)

- uncontrollable twitching or jerking movements of the arms and legs (*tardive dyskinesia*)
- tingling or numbness in the hands or feet, also known as 'pins and needles' (*paraesthesia*)
- 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, stop taking [Medicine name] and tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- chest pain (*chest pain*)⁹
- **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)**
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (*angioedema*)
- convulsions, fits or seizures (*convulsions, fits, seizures*)
- coma (*coma*)
- any other very serious conditions, as per PI

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 occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

⁹ Depending on the adverse reaction listed in your PI, this may be more applicable in the second column.

You may not experience any of them.¹⁰

After using [Medicine name]

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

Storage

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

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

Keep your tablets/capsules in a cool dry place where the temperature stays below 30°C.¹¹

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 30°C.

Disposal

If your doctor or pharmacist tells you to stop taking [Medicine name] or the tablets/suppositories/eyedrops/ointments

¹⁰ Consider placing this statement at the beginning of this section.

¹¹ Reference to 25°C may be more applicable.

[Medicine name]

t has/have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

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

What it looks like

Ingredients

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.