

# [Medicine name]<sup>®</sup> *(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

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## Consumer Medicine Information

Consumer Name  
Consumer Address  
Consumer Address

*Date of Dispensing*

Pharmacist Name  
Pharmacist Address  
Pharmacist Address

### What is in this leaflet<sup>1</sup>

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<sup>2</sup>.

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 using [Medicine name], the therapeutic indications (that is, what it is used for), the pharmacotherapeutic group and how it works etc.*

[Medicine name] is used to open up the airways in people who have asthma. Asthma is a disease where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, smoke or other irritants<sup>3</sup>.

It may also be used to treat emphysema, bronchitis or other breathing problems.

It may be especially helpful at night or before exercise to keep your air passages open if you start to wheeze or have difficulty breathing each time you exert yourself.

*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.

<sup>3</sup> This last sentence is optional. You may also like to add other irritants.

*If a prescription-only medicine:*

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

*Use in children statement<sup>4</sup>:*

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

*Alternative explanation:*

[Medicine name] is not recommended for use in children (under the age of x), as there is no/not enough experience with the use of [Medicine name] in children.

### Before you use [Medicine name]

#### **When you must not use it**

*(as per PI):*

**Do not use Medicine Name if:**

#### **1. you have an allergy to:**

- Medicine Name or any other medicines used to treat breathing problems
- aminophylline, theophylline or caffeine
- any of the ingredients listed at the end of this leaflet

<sup>4</sup> Consider this position if use in children is not a contraindication. Will need to test to determine the most appropriate location.

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

<sup>2</sup> The reference to pharmacists may be especially relevant for S3 medicines.

- Symptoms of an allergic reaction to these medicines may include:

- *list as per PI*

**2. you have or have had heart problems.**

**3. you have or have had thyroid problems.**

*Any other contraindications as per PI.*

*If pregnancy a contraindication:*

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

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

*Alternative explanation:*

Like most ..... medicines, [Medicine name] is not recommended for use during pregnancy, unless you and your doctor or pharmacist have discussed the risks and benefits involved.

[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 ..... 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.

*If use in children a contraindication:*

**Do not give [Medicine name] to a child under x years, unless**

[Medicine name]

**directed to by the child's doctor or pharmacist.**

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

*Tampering and expiry date warnings:*

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

**If you are not sure whether you should start using [Medicine name], contact your doctor or pharmacist.**

***Before you use 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 ..... 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.

[Medicine name] may affect your developing baby if you use it during pregnancy. If it is necessary for you to use [Medicine name], your doctor or pharmacist will discuss the risks and benefits of using it 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 ..... medicines, [Medicine name] is not recommended while you are breast-feeding.

Like most ..... medicines, [Medicine name] is not recommended while you are breast-feeding. If there is a need to consider [Medicine name] while you are breast-feeding, your doctor or pharmacist will discuss with you the benefits and risks of using it.

**Tell your doctor or pharmacist if you have or have had any of the following medical conditions:**

- tuberculosis (TB) or any other lung disease
- a viral or bacterial infection, including lung infections
- stomach ulcer
- reflux
- a fast or irregular heart beat, or any other heart problems
- liver problems
- high blood pressure
- diabetes
- an overactive thyroid gland
- *any others, as per PI.*

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

***Taking other medicines***

*For relieving medicines:*

**Tell your doctor or pharmacist if you are using 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:

- medicines used to treat hayfever, coughs and colds
- medicines used for weight reduction purposes

- vaccine for the flu
- erythromycin, clarithromycin, ciprofloxacin, enoxacin or rifampicin, antibiotics used to treat infections
- thiabendazole, a medicine used to treat some parasitic (worm) infections
- cimetidine, a medicine used to treat stomach reflux and ulcers
- allopurinol, a medicine used to treat gout
- propranolol, mexiletine and verapamil, medicines used to treat high blood pressure and other heart problems
- tacrine, a medicine used to treat dementia in Alzheimers Disease
- phenytoin, phenobarbitone and carbamazepine, medicines used to treat epilepsy and fits or convulsions
- lithium or fluvoxamine, medicines used to treat some forms of depression
- propylthiouracil, a medicine used to treat an overactive thyroid gland
- oral contraceptives
- interferon
- ephedrine
- alcohol, tobacco or marihuana
- *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 use different medicines. Your doctor or pharmacist will advise you.

**If you are not sure if you are taking any of the above medicines, ask your doctor or pharmacist.**

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while using [Medicine name].

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## How to use [Medicine name]

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*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*

[Medicine name]

*information are suggested but may not be necessary in all cases.*

### **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. This depends on your condition and whether or not you are taking any other medicines.

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

They/These directions 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. Do not chew the tablets/capsules.**

The tablets/capsules have a special coating to stop them dissolving until they have passed through the stomach into the intestines where they work. Chewing them destroys the coating.

### **When to take it**

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

*Some examples from the Second Edition of the Usability Guidelines:*

**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.

*Alternatives:*

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].

**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.

### **If you forget to use it**

**If it is almost time for your next dose (within x hours), skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, use 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.**

### **How long to use it**

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

the medicine for as long as your doctor or pharmacist tells you.

Do not stop using it unless your doctor or pharmacist tells you to - even if you feel better.

### **If you take too much (overdose)<sup>5</sup>**

**Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26)<sup>6</sup>, or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have used too much [Medicine name]. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention<sup>7</sup>.

If you take too much [Medicine name], you may get shaky hands, feel sick, anxious, tense, restless, excited and unable to sleep, or get a headache. (*Any others, as per PI*).

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## **While you are using [Medicine name]**

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### **Things you must do**

**If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.**

**If you find that the usual dose of [Medicine name] is not giving as much relief as before, or you are needing to use it more often, please contact your doctor so that your condition can be checked<sup>8</sup>.**

This is important to ensure your breathing problem is controlled properly.

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<sup>5</sup> This section may only be applicable to the relieving medicines.

<sup>6</sup> Consider including the relevant New Zealand telephone numbers here.

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

<sup>8</sup> Testing will determine if this is the best place for this paragraph.

**Continue taking [Medicine name] for as long as your doctor or pharmacist tells you.**

**Visit your doctor regularly to check on your asthma condition.**

**Make sure you keep [Medicine name] with you at all times.**

*Any other precautions or warnings as per PI.*

**Tell any other doctors, dentists, and pharmacists who are treating you that you are using [Medicine name].**

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

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

**If you become pregnant while using [Medicine name], tell your doctor or pharmacist.**

### **Things you must not do**

**Do not take any other medicines for your breathing problems without checking with your doctor.**

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

**Do not use [Medicine name] to treat any other complaints unless your doctor or pharmacist tells you to. Do not stop using [Medicine name], or lower the dosage, without checking with your doctor or pharmacist.**

*For some relieving medicines:*

**Do not use [Medicine name] to relieve acute attacks of asthma. If you become wheezy or tight in the chest before your next dose of [Medicine name] is due, use a 'reliever puffer' in the usual way.**

*Any others, as per PI.*

## **Things to be careful of**

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

As with other ..... 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 precautions as per PI.*

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## **Side effects**

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

*The side effects in the CMI can be arranged in order of potential severity or frequency, depending on which is more appropriate for the product.*

*Outlined below is the format as recommended by the Second Edition of the Usability Guidelines:*

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

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<sup>9</sup>.

**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:**

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<sup>9</sup> Some medicines might need a statement concerning the increased risk of side effects in the elderly.

- headache
- drowsiness
- feeling anxious, nervous, restless or upset
- difficulty sleeping
- dizziness
- sweating
- trembling or shakiness
- aching, twitching or cramping muscles
- unpleasant taste in your mouth
- loss of appetite
- stomach pain
- nausea or vomiting
- diarrhoea
- flushing
- skin rash

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:**

- high sugar (glucose) levels in the blood. Symptoms include passing large amounts of urine, excessive thirst and having a dry mouth and skin
- dizziness or feeling light-headed, which may be caused by low blood pressure
- high blood pressure
- rapid breathing
- fast, pounding or irregular heart beat
- changes in the amount of urine produced by your body
- hair loss

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 casualty at your nearest hospital:**

- blood in your urine
- blood in your vomit

- bloody or tar-like bowel movements
- fits, seizures or convulsions

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

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

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.<sup>10</sup>

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## After using [Medicine name]

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*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.**

**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.

### Disposal

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<sup>10</sup> Consider placing this statement at the beginning of this section.

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

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## Product description

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*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.**