

[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 Using [Medicine name] against the benefits they expect it will have for you.

If you have any concerns about Using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

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] is inhaled into the lungs for the treatment of 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 irritants³.

For preventive medicines⁴:

[Medicine name] acts directly on your air passages to reduce inflammation. This helps to improve your condition and to prevent asthma attacks from occurring. It is a 'preventer' and needs to be taken regularly.

[Medicine name] belongs to a family of medicines called corticosteroids.

For short-acting relieving medicines:

[Medicine name] opens up the air passages in people suffering from asthma, bronchitis and other

³ This last sentence is optional. You may also like to add other irritants.

⁴ Throughout the core document, the 'preventers' refer only to the corticosteroids.

breathing problems. It may also be used before exercise to keep your air passages open if you start to wheeze or have difficulty breathing each time you exert yourself.

[Medicine name] belongs to a family of medicines called beta-2-agonists. These work rapidly to open up the air passages in your lungs.

Optional (if in PI):

[Medicine name] is a 'reliever' drug and you should only use it when you need it.

For long-acting relieving medicines:

[Medicine name] keeps the air passages open in people who need to take medicine every day for breathing problems due to chronic asthma. It is not used to treat an acute asthma attack. It may be especially helpful if you have difficulty breathing 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.

[Medicine name] is used together with other medicines called corticosteroids.

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.

Use in children statement⁵:

[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):

For preventing medicines and long-acting relieving medicines:

Do not use [Medicine name] if you have an allergy to [Medicine name] or any of the ingredients listed at the end of this leaflet
Symptoms of an allergic reaction may include... *(as per PI)*

Do not use [Medicine name] to treat an acute asthma attack.

For short-acting relieving medicines:

Do not use Medicine Name if:

⁵ Consider this position if use in children is not a contraindication. Will need to test to determine the most appropriate location.

[Medicine name]

1. you have an allergy to:

- Medicine Name or any other medicines used to treat breathing problems
- any other beta-2-agonist medicine
- any of the ingredients listed at the end of this leaflet

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 use in children a contraindication:

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

For preventing medicines:

Tell your doctor or pharmacist if you currently have an infection.

If you take Medicine Name while you have an infection, the

medicine may hide some of the signs of an infection. This may make you think, mistakenly, that you are better or that it is not serious.

Tell your doctor or pharmacist if you have or have had tuberculosis (TB).

Any others, as per PI.

For relieving medicines:

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

- heart problems
- liver problems
- diabetes
- high blood pressure
- glaucoma
- 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].

Using other medicines

For preventing 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.

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 heart problems
- medicines used to treat depression or other mood disorders

- medicines used to treat glaucoma, including those that are eye drops
- medicines used to treat hayfever, coughs and colds
- medicines used for weight reduction purposes
- medicines used to treat high blood pressure
- *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.

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

How to use [Medicine name]

As each inhaler is used differently, refer to the pack leaflet. Consider restating what is in the pack leaflet, or its major points, here.

If you are not sure how to use an inhaler, ask your doctor or pharmacist.

Children should only use their inhaler with the help of an adult.

Alternative statement (for short-acting relievers):

Children should only use their inhaler on medical advice and with the help of an adult.

If you find it difficult to breathe in and use your inhaler at the same time, talk to your doctor or pharmacist. They may be able to recommend another method.

When to use it

Include time with respect to dosing intervals, etc.

For preventing medicines only:

Use [Medicine name] at the same time every day.

If you forget to use it

This section is not necessary for relieving medicines.

For long-acting preventive medicines:

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

Otherwise, use it as soon as you remember, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

For preventive medicines:

If you forget to use your [Medicine name] inhaler, use it as soon as you remember, and then go back to using your medicine as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

How long to use it

For preventing medicines:

[Medicine name] helps control your condition. Therefore you must use [Medicine name] every day. Continue using 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.

For short-acting relieving medicines:

[Medicine name] helps control your condition, but does not cure it. Therefore you must continue using the medicine for as long as your doctor or pharmacist tells you.

For long-acting relieving medicines:

[Medicine name] helps control your condition, but does not cure it. Therefore you must use [Medicine name] every day. Continue using 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)⁶

Telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26)⁷, 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 attention⁸.

If you use too much [Medicine name], you may feel sick or vomit, have a fast or irregular heartbeat, tremble, feel shaky, agitated, anxious, tense, restless, excited and unable to sleep. (Any others, as per PI). These symptoms are usually mild side effects of using [Medicine name]. However, if they are severe or do not go away, it may be that you have taken too much [Medicine name].

While you are using [Medicine name]

Things you must do

⁶ This section may only be applicable to the relieving medicines.

⁷ Consider including the relevant New Zealand telephone numbers here.

⁸ The reference to Accident and Emergency and urgent medical attention could be left out, depending on the type of product.

[Medicine name]

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

For relieving medicines:

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 checked⁹.

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

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

Visit your doctor regularly to check on your asthma condition.

Additional paragraph for short-acting relieving medicines:

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

⁹ Testing will determine if this is the best place for this paragraph.

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 long-acting 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.

Tell your doctor or pharmacist if you notice that you have a sore mouth, throat or tongue, sore, creamy-yellow, raised patches in the mouth or a hoarse voice.

These problems are less likely to happen if you use a spacer or rinse your mouth out each time after using [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 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 effects¹⁰.

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

If you get any side effects, do not stop using [Medicine name] without first talking to your doctor or pharmacist.¹¹

For preventive medicines:

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

- sore, creamy-yellow, raised patches in the mouth (thrush)
- hoarse voice
- sore mouth, throat or tongue
- headache
- tiredness
- feeling light-headed
- thirsty
- unpleasant taste in your mouth
- nausea
- diarrhoea
- rash
- weight gain

These side effects are usually mild.

¹⁰ Some medicines might need a statement concerning the increased risk of side effects in the elderly.

¹¹ Consider using this statement for products that have withdrawal symptoms on abrupt cessation.

[Medicine name]

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:

- bruising
- feeling nervous or restless
- mood changes

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

For relieving medicines:

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

- sore mouth, throat or tongue
- dry mouth
- coughing
- headache
- drowsiness
- feeling anxious, nervous, restless or upset
- difficulty sleeping
- dizziness or lightheadedness
- flushing
- sweating
- trembling or shakiness
- aching or weak muscles
- cramps
- tingling or numbness in the hands and feet (also known as 'pins and needles')
- unpleasant taste in your mouth
- nausea or vomiting
- diarrhoea
- rash or itchy skin
- sore or puffy eyes

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:

- difficulty breathing or worsening of your breathing problems
- swelling or severe rash
- fast or irregular heart beat
- pounding heart beat

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

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.¹²

After using [Medicine name]

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

Cleaning

Clean and dry your inhaler each time you use it.

It is important to keep your inhaler clean and dry. It may not work as well if it gets dirty. Follow the instructions at the end of this leaflet/in the pack for cleaning your inhaler.

For Turbuhalers:

The Turbuhaler must be wiped with a clean, dry tissue and must never get wet.

Storage

Keep your inhaler in a cool dry place where the temperature stays below 30°C.

¹² Consider placing this statement at the beginning of this section.

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

If your doctor or pharmacist tells you to stop using [Medicine name] or it has passed its expiry date, ask your pharmacist what to do with any that are left over. Do not puncture the container or throw it into a fire.

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*

[Medicine name]

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.