

[Medicine name][®] *(If you want to include phonetic spelling, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).*

Generic name

Consumer Medicine Information

Date of Dispensing

*Consumer Name
Consumer Address
Consumer Address*

*Pharmacist Name
Pharmacist Address
Pharmacist Address*

General notes:

The 3-column format and the headings and subheadings in this core CMI are as described in the Second Edition of the Usability Guidelines. Under each heading are sample statements that are intended to help you to choose appropriate text for your product-specific CMI.

A glossary of plain-English terms for symptoms of disease and side effects is available from Medicines Australia and ASMI.

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

To improve readability, avoid repeating the product name excessively throughout the CMI. Use the product name wherever there is a major heading such as "Using Medicine name"; then, throughout that section, use words such as "your medicine", "this medicine" or "it", as appropriate. If there is a major heading such as "Side effects" that doesn't include the product name, use the product name in the first paragraph within that section, then proceed as before. In a very long section such as "How to take Medicine name", you may want to repeat the product name once or twice.

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

Wherever the word "take" or "taking" appears, substitute "use" / "using" for topical preparations or self-administered injectables. For products that are not self-administered, use "have", "having" or "given", or similar.

Always use the active voice and bold text for instructions. Any explanation should follow in plain text.

Take care to keep an instruction and explanation together on the page. Do not let them run into the next column or next page unless you add "(continued)" where the break in text appears.

If the product is an S3, you may want to revise the use of "doctor" and "pharmacist" more appropriately throughout the CMI.

Refer to the Second Edition of the Usability Guidelines for exact formatting specifications.

What is in this leaflet

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.

or

Keep this leaflet (use this if the consumer does not keep the medicine at home).

You may need to read it again.

What [Medicine name] is used for

Include information on the therapeutic indications (that is, what it is used for), the expected effects of using the product (if applicable), the pharmacotherapeutic group and how it works etc.

This medicine/Your medicine/Name of active ingredient is used to treat (*insert indication*).

- *List multiple indications in dot points*

This medicine/It belongs to a group of medicines called (*insert therapeutic or pharmacological class*).

This medicine/It works by (*insert a brief plain-English description of how the medicine works*).

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Below are further statements that can be included in this section.

This medicine is/is not addictive.

If the product is addictive, you may want to include symptoms of addiction under Side effects. You may also need a statement on the dangers of abrupt withdrawal (see "Things you must not do" for an example).

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

If the product does affect alertness, include text under "Things to be careful of" instead.

There is not enough information to recommend the use of this medicine for children under the age of x years.

You may want to include this here if the product is not approved for use in children but is not specifically contraindicated. However, for some products where there is considerable unapproved use in children, you may prefer not to include any text. Note: If the product is contraindicated, include text under "When you must not take it" in the next section.

Before you take/use/have/are given [Medicine name]

When you must not take it

Include all Contraindications that appear in the PI (examples below)

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

- any medicine containing (*active ingredient*)
- any of the ingredients listed at the end of this leaflet.

- any other similar medicines (*such as medicines of the same class or with a similar structure, as per PI*).

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- *add any other specific reactions listed in the PI.*

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in [Medicine name] passes into breast milk (*if applicable*) and there is a possibility that your baby may be affected.

Do not give this medicine/it to a child under the age of x years.

Safety and effectiveness in children younger than x years have not been established.

Any other contraindications as per PI.

Do not take this medicine/it after the expiry date printed on the pack or 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 this medicine, talk to your doctor.

Before you start to take it

Include all relevant information from the Precautions section of the PI (examples below). Do not duplicate any information from the previous section.

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- *use dot points to list relevant conditions as per PI*

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

(place text here if pregnancy and breast-feeding are a precaution but not a contraindication).

Any other precautions, as per PI.

If you have not told your doctor about any of the above, tell him/her 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 get without a prescription from your pharmacy, supermarket or health food shop.

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

Insert any specific interactions as dot points, as per PI. Avoid long lists of dot points by grouping similar medicines whenever possible. Include what they are used for.

- (*example*) medicines used to treat high blood pressure such as
- (*example*) medicines used to treat depression such as ...
- (*example*) warfarin, a medicine used to prevent blood clots

These medicines may be affected by [Medicine name] or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take [Medicine name]

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.

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

How much to take

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

How to take it

Include any special precautions (examples below).

Swallow the tablets/capsules whole with a full glass of water.

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 your medicine at about the same time each day.

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

It does not matter if you take this medicine before or after food.

Take your medicine on an empty stomach, for example, 1 hour before food or 2 hours after food.

Food can interfere with the absorption of this medicine.

Include any relevant interactions that require a change in the way a medicine is taken (example below)

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.

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

Continue taking your medicine until you finish the pack.

Stop using this medicine when the redness and itching have gone.

If you forget to take it

If it is less than ‘x’ hours before 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 that you missed.

(possible explanation) 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)

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

Include the relevant New Zealand telephone number if appropriate.

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, 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 attention.

Symptoms of an overdose may include *(list symptoms as per 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. Add additional information as per PI.

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor’s appointments so that your progress can be checked.

Your doctor may do some tests *(add specific tests as per PI)* from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects such as (*effects of abrupt withdrawal as per PI*). If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Any other instructions, as per PI.

Things to be careful of

Include relevant information to help the consumer use the product safely (examples below).

Depending on the product, you may wish to include precautions on driving and drinking alcohol under "Things you must not do" rather than in this section.

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

This medicine may cause (*dizziness, light-headedness, tiredness, drowsiness, etc. as per PI*) in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. (*if appropriate, add "Children should be careful when riding bicycles or climbing trees.*)

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, (*symptoms as per PI e.g. dizziness or light-headedness*) may be worse. (*can also include other medicines that affect alertness such as antihistamines, as per PI*).

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.

Any other instructions, as per PI.

The following subheading and text may be added as needed.

Things that would be helpful for

(e.g. your blood pressure, heart failure, diabetes).

Some self help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

Add helpful hints relevant to the product.

Side effects

Suggested general statements to precede the lists of specific side effects:

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

This medicine 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 attention 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. (*if there is an increased risk of side effects in the elderly*).

Do not be alarmed by the following lists of side effects. You may not experience any of them.**Ask your doctor or pharmacist to answer any questions you may have.**

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

Take care to include only those symptoms that the consumer can detect and do something about (refer to glossary of plain-English terms available from the Medicines Australia and ASMI websites).

The following possible side effect lists are placed in order of increasing urgency of the behaviour required. You may need to include one or more lists, depending on the PI.

Take care not to duplicate side effects in more than one list so the consumer

is not confused about the action that is required.

Add side effects in dot points, grouping like symptoms to keep the lists as short as possible.

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

- *side effects, as per PI*

The above list includes the more common side effects of your medicine. They are usually mild and short-lived (*if consistent with the PI*).

Tell your doctor as soon as possible if you notice any of the following:

- *side effects, as per PI*

The above list includes serious side effects that may require medical attention. Serious side effects are rare (*if consistent with frequencies in the PI*).

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

- *side effects as per PI*

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare (*if consistent with the frequencies in the PI*).

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

(if some side effects have no symptoms, you can add) Some of these side effects (for example, changes in thyroid function, cholesterol level or blood pressure as per PI) can only be found when your doctor does tests from time to time to check your progress.

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 may 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.

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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes (*include any that are appropriate*).

Manufacturer/Distributor/Supplier

(use appropriate heading)

[Medicine name] is made/distributed/supplied in Australia by:

Include name and address of sponsor

® = Registered Trademark *or*

™ = Trademark (*if appropriate*)

This leaflet was prepared in month/year.

Include AUST R number(s)

You may want to include a document code and/or a reference to the approved PI.

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 colour, markings, any tablet scoring, colour and consistency of liquids, pack sizes, etc.

Ingredients

[Medicine name] contains x mg of (*generic name*) as the active ingredient.

It also contains:

- *list excipients in dot points*

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