

Medicine Name[®] (*phonetic spelling if required*)

Generic name

Consumer Medicine Information

Name
Address
Address

What is in this leaflet¹

Standard information as suggested in Usability Guidelines

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 benefits². Your doctor has weighed the risks of you taking Medicine Name against the benefits they expect it will have for you.

Alternative:

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Medicine Name against the benefits this medicine is expected to 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.

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

² Consider reversing "risks" and "benefits"

What Medicine Name is used for

The name of your medicine is Medicine Name. It contains the active ingredient called (generic name)³.

Ulcers:

Medicine Name is used to treat / help heal peptic ulcers.

Depending on the position of the ulcer it is called a gastric or duodenal ulcer. A gastric ulcer occurs in the stomach. A duodenal ulcer occurs in the duodenum which is the tube leading out of the stomach.

These can be caused in part by too much acid being made in the stomach.

Medicine Name is also used to help stop duodenal ulcers from coming back.

Reflux oesophagitis:

Medicine Name is used to treat reflux oesophagitis or reflux disease. This can be caused by "washing back" (reflux) of food and acid from the stomach into the food pipe, also known as the oesophagus.

Reflux can cause a burning sensation in the chest rising up to

³ Consider mentioning the Medicine Name and active ingredient early in the CMI, perhaps under "What is in this leaflet".

the throat, also known as heartburn.

Alternative:

Medicine Name is used for the burning indigestion pain (heartburn) caused by the acid stomach contents flowing the wrong way back up the food pipe, known as reflux oesophagitis.

Gastroparesis:

Medicine Name is used for the discomfort caused by a slow moving stomach known as gastroparesis. For example, not being able to finish a meal, a feeling of being "too full" or bloated after a meal, a loss of appetite, feeling sick and maybe vomiting, or belching without relief.

Gastro-oesophageal reflux in children:

The discomfort caused to babies and children when they excessively bring up their stomach contents after feeding known as gastro-oesophageal reflux. Medicine Name is used when other treatments have failed to bring relief.

Other treatments include thickened feeds and keeping the infant or child upright for a while after feeding.

For Zollinger-Ellison syndrome:

Medicine Name is also used to treat a rare condition called Zollinger-Ellison syndrome, where the stomach produces very large

amounts of acid, much more than in ulcers and reflux disease.

For scleroderma oesophagitis:

Medicine Name may be used to treat scleroderma oesophagitis. Scleroderma is a rare condition, and in scleroderma oesophagitis the food pipe is abnormal and there is reflux.

How Medicine Name works

H₂ antagonists or H₂ blockers:

Medicine Name belongs to a group of medicines called H₂ antagonists or H₂ blockers.

Medicine Name works by decreasing the amount of acid made by the stomach. This helps reduce the pain and also allows the ulcer and/or reflux disease to heal in most people.

Proton pump inhibitors:

Medicine Name belongs to a group of medicines called proton pumps inhibitors (PPIs).

Medicine Name works by decreasing the amount of acid the stomach makes, to give relief from the symptoms and allow healing to take place.

Prokinetic agents:

Medicine Name works by strengthening the muscle contractions of the digestive tract. Food then moves more easily through the stomach.

Cytoprotectant:

Medicine Name works by forming a layer over the ulcer to help protect it from the stomach contents.

Non-approved use:

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.

or:

There is no evidence that Medicine Name is addictive.

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

**Before you take
Medicine Name**

or

**Before you use
Medicine Name**

***When you must not take it
When you must not use it***

Do not take/use Medicine Name if:

1. you have an allergy to:

- Medicine Name
- any of the ingredients listed at the end of this leaflet⁴.

Symptoms of an allergic reaction include:

- *list as per PI*

*Pregnancy and breast-feeding*⁵:

2. you are pregnant, or intend to become pregnant.

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

3. you are breast-feeding or intend to breast-feed.

Medicine Name passes into breast milk and may affect your baby.

⁴ *May be included under 'Before you start to take Medicine Name' as an alternative or in addition to this section*

⁵ *Consider including pregnancy and breast-feeding statements here or under 'Before you start to take it'.*

Alternative

Medicine Name passes into breast milk. The effect on the baby is unknown.

Tampering and Expiry Date Warnings.

Do not use Medicine Name if the packaging is torn or shows signs of tampering.

or

Do not take/use Medicine Name after the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date it may have no effect at all, or worse, an unexpected effect.

Do not take/use Medicine Name after the expiry date (EXP) printed on the pack has passed.

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

If you are not sure whether you should start taking/using Medicine Name, talk to your doctor.

Before you start to take it

You must tell your doctor if:

1. you have any allergies to:

- Medicine Name
- any of the ingredients listed at the end of this leaflet
- any other substances, such as foods, preservatives or dyes

2. you intend to become pregnant or intend to breast-feed.

Medicine Name should not be used during pregnancy or while breast-feeding.

3. you have or have had any other medical conditions, including:

- *list as per PI*

If you have not told your doctor about any of the above, tell them before you take Medicine Name.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Medicine Name. These include:-

- list 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 will advise you.

How to take Medicine Name

or

How to use 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:

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.

How to take it

Include taking with water or any special precautions regarding throat irritation, if appropriate.

When to take it

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

How long to take it

as appropriate

If you forget to take it

As per Usability Guidelines

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 it as you would normally.⁶

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26)⁷ for advice, or go to casualty 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 attention.⁸ Keep telephone numbers for these places handy.

If you take too much Medicine name, you may feel ... *(list symptoms in PI)*

While you are taking Medicine Name

or

While you are using Medicine Name

Things you must do

Use Medicine Name exactly as your doctor has prescribed.

Tell your doctor (immediately)⁹ if you become pregnant while you are taking Medicine Name.

Tell all doctors, dentists and pharmacists who are treating you that you are taking Medicine Name.

Alternative:

Tell your doctor or pharmacist that you are taking Medicine Name if you are about to be started on any new medicines¹⁰

Things you must not do¹¹

Do not give Medicine Name to anyone else, even if they have the same symptoms as you.

Do not use Medicine Name to treat any other complaints unless your doctor tells you to.

Things to be careful of

(for H₂A only):

Be careful driving or operating machinery until you know how Medicine Name affects you.

⁹ Use "immediately" if appropriate to the product.

¹⁰ This is a complimentary drug interaction statement to that included under "Before you use/take Medicine Name."

¹¹ The Usability Guidelines recommend including the following two statements under "Before you take it", but consider including them here under "While you are using Medicine Name."

Medicine Name generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Medicine Name may cause dizziness or light-headedness 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 you drink alcohol, dizziness or light-headedness may be worse.

Things that may help your condition

Some self help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol** - your doctor may advise you to limit your alcohol intake.
- **Aspirin and many other medicines used to treat arthritis/period pain/headaches** - these medicines may irritate the stomach and may make your condition worse. Your doctor or pharmacist may suggest other medicines you can take.
- **Caffeine** - your doctor may advise you to limit the number of drinks which contain caffeine, such as coffee, tea, cocoa and cola drinks, because they contain ingredients that may irritate your stomach.
- **Eating habits** - eat smaller, more frequent meals. Eat slowly and chew your food carefully. Try not to rush at meal times.
- **Smoking** - your doctor may advise you to stop smoking or at least cut down.

- **Weight** - your doctor may suggest losing some weight to help your condition.

Side effects

Only the opening general statements will be consistent in this section. Other statements will be product specific and consistent with the approved Product Information.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Medicine Name.

Medicine Name helps most people with peptic ulcers or reflux disease, but it may have unwanted side effects in a few people.

All medicines 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.

Alternative:

Check with your doctor as soon as possible if you have any problems while taking Medicine Name, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Medicine Name can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

Ask your doctor or pharmacist any questions you may have.

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

- *list as per PI*

These side effects are usually mild.

or

These are the more common side effects of Medicine Name.

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

- *list as per PI*

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

If any of the following happen, tell your doctor immediately or go to casualty at your nearest hospital.

- *list as per PI*

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

Other side effects not listed above may occur in some patients. Tell your doctor if you notice anything making you feel unwell when you are taking, or soon after you have finished taking, Medicine Name.

or

Some people may get other side effects while taking, or soon after taking, Medicine Name.

Possible additional statement:

Other problems are more likely to arise from the ulcer itself rather than the treatment. For this reason, contact your doctor immediately if you notice any of the following:

- pain or indigestion occurring during treatment with Medicine Name
- you begin to vomit blood or food
- your pass black (blood-stained) motions

Ask your doctor or pharmacist if you do not understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

After using Medicine Name

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

Storage

Keep your tablets in their blister pack / bottle / other packaging until it is time to take them.

If you take the tablet out of the box or the blister pack they may not keep well.

Keep Medicine Name in a cool dry place where the temperature stays below 30°C. Do not store Medicine Name or any other medicines in a bathroom or near a sink. Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Medicine Name where young 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 Medicine Name or the tablets / capsules etc have passed their expiry date, ask your pharmacist what to do with any tablets / capsules etc that are left over.

Product description

This information will be product specific. The Usability Guidelines suggest the information should be presented in the following order:

What it looks like

Ingredients

Medicine Name does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Manufacturer / Distributor / Supplier

Include:

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

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 Usability Guidelines wherever possible.