

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 benefits. 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 benefits². 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.

Medicine Name is used to prevent angina.

Alternatives:

Medicine Name is used to prevent angina, but it is not for the relief of a sudden attack of angina.

Medicine Name is used to treat angina.

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart.

The pain of angina is usually brought on by exercise or stress.

Alternative:

Angina is a pain or uncomfortable sensation in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. The pain of angina is due to a shortage of oxygen to the heart.

For nitrates:

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

Medicine Name belongs to a group of medicines called nitrates. It works by widening blood vessels, letting more blood and oxygen reach the heart.

For calcium channel blockers:

Medicine Name belongs to a group of medicines called calcium channel blockers or calcium antagonists. They work by opening up blood vessels and letting more blood and oxygen reach the heart.

They do not change the amount of calcium in your blood or bones.

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.

Use in children statement⁴:

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.

Statement about addictive properties:

Medicine Name is not addictive.

or

There is no evidence that Medicine Name is addictive.

⁴ Consider this position if use in children is not a contraindication. Testing indicated that this information is more easily found under "When you must not take it".

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 or any of the ingredients listed at the end of this leaflet
- any medicine or food containing nitrates or nitrites (*nitrites only*)

Symptoms of an allergic reaction to these medicines may include:

- asthma, wheezing or shortness of breath
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- hives, itching or skin rash
- fainting

Pregnancy and breast-feeding⁵:

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.

Alternative

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

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

Others, as per PI.

Tampering and expiry date warnings:

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

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

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

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

If use in children a contraindication:

Do not give Medicine Name to a child under x years.

The safety and effectiveness of Medicine Name have not been established in children.

Before you start to take/use it

Tell your doctor if:

1. you have any allergies to:

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

2. you are pregnant or intend to become pregnant.

Your doctor will discuss the risks and benefits of using Medicine name during pregnancy.

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

Your doctor will discuss the risks and benefits of using Medicine name during breastfeeding.

4. you have or have had any medical conditions, especially the following:

- *List as per PI.*

Taking other medicines

Tell your doctor 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 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 to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking Medicine Name.

Alternative:

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking/using Medicine Name with other medicines.

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/use

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.

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 special precautions, if appropriate.

Swallow Medicine Name with a glass of water.

Alternatives:

If you are taking the dispersible tablets, allow the tablets to dissolve in a glass of water, then drink it straight away.

Swallow Medicine Name whole with a full glass of water. Do not chew them.

The tablets have a special coating to stop them dissolving until they have passed through the stomach into the bowel. Chewing them would destroy the coating.

When to take it

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

Take the tablets/capsules with or straight after food with a full glass of water.

This may help reduce the possibility of stomach upset.

How long to take/use it

As appropriate

If you are not sure how long to take/use your Medicine Name, talk to your doctor.

If you forget to take/use it
As per Usability Guidelines

If it is almost time for your next dose, skip the dose you missed and take/use your next dose when you are meant to. Otherwise, take/use it as soon as you remember, and then go back to taking/using your tablets as you would normally⁶.

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

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

If you take/use too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26)⁷, or go to casualty at your nearest hospital, if you think that you or anyone else may have taken/used too much Medicine Name. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention⁸. Keep these telephone numbers handy.

If you take/use too much Medicine Name, you may feel (*list symptoms in PI*)

While you are using Medicine Name

Things you must do

Use Medicine Name exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, you may not get relief from your attacks of angina.

Tell your doctor if you continue to have angina attacks or if they become more frequent while you are using Medicine Name.

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

Tell your doctor or pharmacist that you are taking Medicine Name if you are about to be started on any new medicines.⁹

Things you must not do

This information will be product specific, for example depending on whether the product is to relieve acute attacks or prophylactic.

Do not use it to treat any other complaints unless your doctor says to.¹⁰

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

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

Medicine Name may cause dizziness and fainting (*add other effects such as blurred vision*) in some patients, especially when you first start to use it. 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 this happens to you.

⁹ This is a complimentary drug interaction statement to that included under "Before you use/take Medicine Name".

¹⁰ The Usability Guidelines recommend including this statement and the one below under "Before you take it", but consider including them here under "While you are using Medicine Name".

⁶ These two sentences are in reverse order from that recommended in the Usability Guidelines.

⁷ Consider including the relevant New Zealand telephone numbers here.

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

Be careful not to overdo physical activities when you first start using Medicine Name.

You may feel better when you start taking it, but you will need time to improve your physical fitness.

Nitrates only:

Get up slowly when getting out of bed or standing up if you feel light-headed, dizzy or faint.

You may feel light-headed or dizzy when you begin to take Medicine Name or if the dose is increased. This is because your blood pressure is falling suddenly. 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. The problem usually goes away after the first few days.

or

If this problem gets worse or continues, talk to your doctor.

Nitrates only:

Be careful when drinking alcohol while you are using Medicine Name.

If you drink alcohol while using Medicine Name your blood pressure may drop, making you feel dizzy or faint.

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 angina, but it may have unwanted 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 treatment if you get some of the side effects.

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, stop taking Medicine Name and 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 or hospitalisation. These side effects are rare.

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

or

Some people may get other side effects while taking/using Medicine Name.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking Medicine Name

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

Storage

Keep your tablets/capsules in their container until it is time to take them.

If you take the tablets (capsules etc) out of their container they may not keep well.

Keep Medicine Name in a cool, dry place where it stays below 30°C. Do not store it, or any other medicine, 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 this medicine 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) 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

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

Medicine Name does not contain lactose, sucrose, gluten, 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.