

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

- Medicine Name is used to treat certain infections caused by bacteria and other organisms / prevent certain infections that may occur during surgery / (*other indications*)

Medicine Name is an antibiotic which belongs to a group of medicines called nitroimidazoles.

Medicine Name works by killing or stopping the growth of bacteria and other organisms causing these infections.

suppositories:

Medicine Name suppositories are used when Medicine Name cannot be given by mouth as tablets / mixture.

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.

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 other nitroimidazoles**
 - **any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction may include skin rash, itching, difficulty breathing...(*as per PI*)
- 2. you have ever had a blood disorder**
- 3. you have a disease of the brain, spinal cord or nerves**
- 4. you are pregnant (unless your doctor says otherwise)**
Your doctor will discuss the risks and benefits of taking / using Medicine Name during pregnancy.
- 5. If you are a woman of child-bearing age, make sure you do not become pregnant while taking / using Medicine Name.**
- 6. you are breastfeeding.**

Like many other medicines, Medicine Name passes into breast milk and may harm your baby.

tinidazole:

Do not breastfeed your baby while taking, and until at least 3 days after stopping Medicine Name.

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

***Before you start to take it
Before you start to use it***

Tell your doctor if:

1. you have any allergies to any other medicines or any other substances such as foods, preservatives or dyes.

2. you have or have ever had any other health problems/ medical conditions including: (as in PI)

- any kidney problems
- any liver problems
- Crohn's disease, an inflammatory disease of the intestines

3. you drink alcohol
Do not drink alcohol during, (and for x days after stopping), treatment with Medicine Name

4. you plan to become pregnant or breastfeed

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking / using Medicine Name.

Taking other medicines

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

Some medicines may interfere with Medicine Name. These include:

(the following is an all inclusive list for both metronidazole and tinidazole; choose those applicable to your PI)

- warfarin, a medicine used to prevent blood clots
- antabuse, a medicine used to reduce the amount of alcohol drunk
- some anticancer medicines such as BCNU or cyclophosphamide
- lithium, a medicine used to treat some types of depression
- corticosteroids such as prednisone or cortisone
- cimetidine, a medicine used to treat ulcers
- phenobarbitone, a medicine to treat convulsions or for sedation

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.

Talk to your doctor about the need for an additional method of contraception while taking/using Medicine Name.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with Medicine Name.³

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

³ This is recommended text from QARG for the potential interaction between antibiotics and oral contraceptives.

Oral:

How to take Medicine Name

This information will be product specific and consistent with the PI. The following order of information is suggested, but will depend upon the particular product and the amount of information. These headings are suggested but may not be necessary in all cases.

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

These / 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.

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 eg "The dose will vary from patient to patient. Your doctor will decide the right dose for you"

The dose for children will depend on body weight / age.

However, depending on your condition and how you react to the medicine, your doctor may ask you to take a different dose.

Oral only:

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.

Suppositories only:

How to use it

Your doctor will tell you how many suppositories you need to use each day.

If possible, go to the toilet and empty your bowels before using your suppository.

Suppositories work best if your bowels are empty.

Follow these steps to use a suppository:

1. Wash your hands thoroughly with soap and water.
2. Feel the suppository while it is still in the foil.
3. If it feels soft, keep it in the foil/plastic, chill it in the fridge or by holding it under cold water for a few minutes. Do not remove the foil/plastic wrapper while you are chilling it.
4. Put on a disposable glove, if desired (available from a pharmacy).
5. Remove all of the foil/plastic wrapper from the suppository.
6. Moisten the suppository by dipping it briefly in cool water.
7. Lie on your side and raise your knee to your chest.
8. Push the suppository (blunt end first) gently into your rectum (back passage).
9. Remain lying down for a few minutes so that the suppository dissolves.
10. Throw away used materials and wash your hands thoroughly.

Try not go to the toilet and open your bowels for at least an hour after using the suppository.

The suppository takes about one hour to be completely absorbed and do its work.

If you are not sure how to use a suppository, ask your doctor or pharmacist.

Oral only:

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

Medicine Name is usually taken / used for ... (as per PI).

However, your doctor may prescribe Medicine Name for longer periods. Check with your doctor if you are not sure how long you should be taking / using it.

Continue taking / using Medicine Name until you finish the pack / bottle or until your doctor recommends.

Do not stop taking / using it because you are feeling better.

If you do not complete the full course prescribed by your doctor, all of the bacteria / organisms causing your infection may not be killed. These bacteria / organisms may continue to grow and multiply so that your infection may not clear completely or may return.⁴

Alternative:

Keep taking / using this medicine for the full time of treatment, even if you begin to feel better after a few days.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you forget to take it

⁴ *Alternatively, place under While you are taking it/ Things you must not do. Testing will determine best location*

If you forget to use it

(as per Usability Guidelines)⁵

If you are taking more than a single dose of Medicine Name, and 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 / use it as soon as you remember, then go back to taking / using it as you would normally.

Do not take / use a double dose to make up for the dose you have 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)⁶ or go casualty at your nearest hospital, if you think 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 attention.⁷ Keep these telephone numbers handy.

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

⁵ *These two sentences are in reverse order to that recommended in the Usability Guidelines*

⁶ *Consider including the relevant New Zealand telephone numbers here.*

⁷ *The reference to casualty and urgent medical attention could be left out, depending on the type of product.*

While you are taking Medicine Name

or

While you are using Medicine Name

Things you must do

If you become pregnant while you are taking / using Medicine Name, tell your doctor immediately.

If the symptoms of your infection do not improve, or if they become worse, tell your doctor.

If you are taking Medicine Name for 10 days or longer, make sure you have any tests of your blood and nervous system that your doctor may request.

If you get a sore, white mouth or tongue while taking / using or soon after stopping Medicine Name, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal / yeast infection called thrush. Sometimes the use of Medicine Name allows fungi / yeast to grow and the above symptoms to occur. Medicine Name does not work against fungi / yeast.

metronidazole:

If you need to have any blood tests, tell your doctor you are using Medicine Name.

Medicine Name may affect the results of some laboratory tests.

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

Things you must not do

Do not drink any alcohol or any alcoholic drinks while taking / using (and for x days after stopping) Medicine Name.

The use of alcohol with Medicine Name may make you feel sick, vomit or have stomach cramps, headaches or flushing.

Do not stop taking / using your tablets / mixture / suppositories because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, all of the bacteria / organisms causing your infection may not be killed. These bacteria / organisms may continue to grow and multiply so that your infection may not clear completely or may return.

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 medical complaints unless your doctor tells you to.⁸

Side effects

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

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

Medicine Name helps most people with infections, 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 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 / using Medicine Name, even if you do

⁸ The Usability Guidelines recommend including this statement and the one above under "Before you take it", but consider including them here under "While you are using Medicine Name".

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 to answer any questions you may have.

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

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- *list other less serious side effects as appropriate*

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 serious side effects as appropriate (hypersensitivity, angioneurotic oedema, neurological side effects)*

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:

- rash, itchiness, hives
- swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing
- tingling or numbness of the hands or feet, or muscle weakness

These are very serious side effects. You may need urgent

medical attention. 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.

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

After taking Medicine Name

or

After using Medicine Name

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

Storage

Keep your tablets/suppositories in the pack/bottle until it is time to take them.

If you take the tablets/suppositories out of the pack/bottle they will not keep well.

Keep the tablets/suppositories in a cool dry place where the temperature stays below 30°C. Do not freeze Medicine Name. Protect Medicine name from light. Do not store Medicine Name or any other medicine in the bathroom or near a sink. Do not leave it in the car 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 tells you to stop taking/using Medicine Name or the tablets/suppositories/gel have passed their expiry date, ask your pharmacist what to do with any 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

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.