

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 infections in different parts of the body caused by bacteria.

list specific indications if desired

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

Medicine Name works by killing or stopping the growth of bacteria causing your infection.

Medicine Name will not work against viral infections such as colds or flu.

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 properties³:

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.

³ Consider using addictive statement if product is used for longterm therapy

Before you take Medicine Name

When you must not take it

Do not take/use Medicine Name if:

1. you have an allergy to:

- **Medicine Name or any other macrolide antibiotic** (*give examples*)
- **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*)

erythromycin, roxithromycin:

2. you have severe liver problems

erythromycin, clarithromycin:

3. you are taking antihistamine medicines such as terfenadine or astemizole

roxithromycin

4. you are taking certain medicines for migraine headache called ergot alkaloids (eg *Migral, Cafergot, Ergodryl, Dihydergot; etc.*)

Ask your doctor if you are not sure if you are taking any of these medicines.

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:

clarithromycin:

Do not give Medicine Name to a child under 12 years.

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

or:

There is not enough information to recommend the use of Medicine Name in children of this age.

azithromycin:

Do not give Medicine Name to children under 16 years unless directed by the child's doctor.

There is not enough information to recommend the use of Medicine Name in children of this age.

roxithromycin:

Do not give Medicine Name to children under 40kg unless directed by the child's doctor.

There is not enough information to recommend the use of Medicine Name in children of this weight.

Before you start to take it

1. You must tell your doctor if:

2. you have any allergies to:

- any other medicines

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

3. if you are pregnant or intend to become pregnant

Like most other medicines, Medicine Name is not recommended in pregnancy. However, your doctor will discuss the possible risks and benefits of taking Medicine Name during pregnancy.

4. if you are breast-feeding or plan to breast-feed.

Like most other medicines, Medicine Name is not recommended in breast-feeding. However, your doctor will discuss the possible risks and benefits of taking Medicine Name during breast-feeding.

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

- any kidney problems (*azithromycin, roxithromycin*)
- any liver problems (*azithromycin, clarithromycin, roxithromycin, erythromycin*)
- *as per PI*

If you have not told your doctor about any of the above, tell them before you take/are given 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 various macrolides. Choose those applicable to your PI.

- theophylline, a medicine used to treat asthma
- some medicines used to treat epilepsy such as
- carbamazepine, phenytoin, and (hexobarbital)
- digoxin, a medicine used to treat heart failure

- warfarin, a medicine used to prevent blood clots
- cyclosporin, a medicine used to prevent organ transplant rejection or to treat certain problems with the immune system
- (alfentanil)
- disopyramide, a medicine to treat irregular heart rhythms
- (lovostatin, a medicine used to lower high blood cholesterol)
- bromocriptine, a medicine used to treat Parkinson's disease
- triazolam or midazolam, medicines used to treat sleep problems
- some medicines for migraine headache such as ergotamine or dihydroergotamine
- terfenadine, astemizole, medicines used to treat allergies
- the antibiotics clindamycin, and lincomycin
- probenecid, a medicine used to treat gout
- antacids, medicines used to treat indigestion
- the contraceptive pill (birth control pill).

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.

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

An alternative explanation which does not list interacting products:

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

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

Medicine Name may decrease the effectiveness of some birth control pills.

Alternative

Talk to your doctor about the need for additional contraception while taking Medicine Name.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with Medicine Name.⁴

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.

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"

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.

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

How to take it

Include taking with water or any special precautions or advice on reconstitution, swallowing without chewing etc.

Swallow Medicine Name with a glass of water.

⁴This is recommended text from QARG for the potential interaction between antibiotics and oral contraceptives.

Alternative:

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 timing regarding food, dosing intervals, night-time dosing etc.

How long to take it

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

Do not stop taking the tablets / capsules / mixture because you are feeling better.

If you do not complete the full course prescribed by your doctor, all of the bacteria causing your infection may not be killed. These bacteria may continue to grow and multiply so that your infection may not clear completely or may return.⁵

Alternative:

Keep taking 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.

For treating infections, Medicine Name is usually taken for ... (as per PI).

for some erythromycin preparations:

⁵ Alternatively, place under 'While you are taking it' or 'Things you must not do'. (Testing will determine best location)

For controlling acne, Medicine Name is normally taken for ... (as per PI).

However, your doctor may prescribe Medicine Name for longer periods.

If you are not sure how long you should be taking Medicine Name, check with your doctor.

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, then go back to taking your tablets / capsules / mixture as you would normally.⁶

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

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

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

⁷ Consider including the relevant New Zealand telephone numbers here.

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

While you are using Medicine Name

Things you must do

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

If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Medicine Name has been stopped

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore, white mouth or tongue while taking, 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.

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

If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Medicine Name.

erythromycin, clarithromycin:

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

Medicine Name may affect the results of some laboratory tests.

azithromycin:

If you are taking an antacid, take it at least one hour before or two hours after your Medicine Name dose to make sure there is no problem with absorption.

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

Things you must not do

Do not stop taking your tablets / capsules / mixture 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 causing your infection may not be killed. These bacteria 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.⁹

Things to be careful of

azithromycin only:

Protect your skin when you are in the sun, especially between 10 am and 3 pm.

Medicine Name may cause your skin to be much more sensitive to sunlight than it is normally. Exposure to sunlight may cause a skin rash, itching, redness, or a severe sunburn.

If outdoors, wear protective clothing and use a 15+ sunscreen. If your skin does appear to be burning, stop taking Medicine Name and tell your doctor.

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

⁹ 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".

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 / drowsiness / tiredness (as per PI) in some people.

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 Medicine Name.

Medicine Name helps most people with bacterial 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 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 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 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.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Medicine Name:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above

These are rare but serious side effects. You may have a serious condition affecting your bowel. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any medicine for this diarrhoea without first checking with your doctor.

Alternative:

These are rare but serious side effects. Medicine Name can change bacteria, which are normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. Therefore, you may need urgent medical attention. However, this side effect is rare.

Do not take any diarrhoea medicine without first checking with your doctor.

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 using Medicine Name

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

Storage

Keep your tablets / capsules in the (blister) pack/bottle until it is time to take them.

If you take the tablets/capsules out of 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 it, or any other medicine, in a bathroom or near a sink. Do not leave them in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Medicine Name 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 Medicine Name, or the tablets / capsules have passed their expiry date, ask your pharmacist what to do with any tablets /capsules 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.

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