

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 an antibiotic used to treat certain infections / control acne / prevent a type of malaria (*depending on PI*)

It belongs to a group of medicines called tetracyclines.

These medicines work by killing or stopping the growth of bacteria which cause infections or make acne worse. They also work against parasites that cause malaria. (*as appropriate*).

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

Non-approved uses:

Your doctor, however, may prescribe Medicine Name for another purpose. Ask your doctor if you have any questions about why Medicine Name has been prescribed for you.

*Statement about addictive properties:*³

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 Medicine Name if:

- 1. you have ever had an allergic reaction to :**
 - medicines containing (*generic name*)
 - medicines containing other tetracyclines
 - any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction to a tetracycline antibiotic may include rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or troubled breathing.

- 2. you are taking preparations containing vitamin A, isotretinoin or etretinate.**

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

Pregnancy and breastfeeding statements:

- 3. you are pregnant or breastfeeding**

As with many medicines, tetracyclines may harm the developing or breastfeeding baby. This may include enamel loss and staining of the child's teeth.

High doses of tetracyclines may also cause liver problems in pregnant women.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking Medicine Name.

Include other contraindications listed in PI.

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

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.

Use in children statement:

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

Medicine Name, like other tetracyclines, may cause enamel loss and staining in developing teeth.

Before you start to take it

You must tell your doctor if:

- 1. you are allergic to any other medicines or other substances such as foods, dyes or preservatives.**

2. you have or have had any other health problems, including:

- *(as per PI)*

3. you plan to become pregnant or to breastfeed.

4. you are scheduled to have surgery under general anaesthetic.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking 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:

- preparations containing Vitamin A
- some medicines used for skin problems such as isotretinoin or etretinate
- warfarin, a medicine used to stop blood clotting
- another group of antibiotics called penicillins
- the contraceptive pill (birth control pill)

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

Your doctor may advise you to use an additional method of contraception while taking Medicine Name.

doxycycline:

- some medicines used in the treatment of epilepsy such as phenytoin, carbamazepine or phenobarbitone.

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.

Some medicines may interfere with the absorption of Medicine Name. These include:

- iron preparations including vitamin preparations that contain iron
- antacids used for indigestion

You can still take these medicines while you are taking Medicine Name. However, you must take Medicine Name at least two hours before or two hours after taking any of these medicines to make sure there is no problem with absorption.

Alternative explanations:

Although certain medicines should not be used together at all, in other cases two different medicines may be used together even though an interaction may occur. In these cases, your doctor may want to change the dose or other precautions may be necessary.

An 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.

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

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 subheadings are suggested but may not be necessary in all cases.

Follow all directions given to you by your doctor and 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.

How much to take

For treating infections, the usual dose of Medicine Name is ... (as in PI)

For controlling acne, the usual dose is ... (as in PI)

For the prevention of malaria, the usual dose is one 100mg tablet each day, commencing two days before entering the malarious area, during the visit, and for two weeks after leaving the area.

Medicine Name is normally used in combination with another antimalarial medicine.

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 regarding throat irritation, if appropriate.

Swallow Medicine Name with a glass of water.

doxycycline and minocycline:

Swallow the tablets whole with a full glass of water or milk while sitting or standing upright.

Do not lie down immediately after swallowing Medicine Name.

It is important to stay upright, for example sitting, standing or walking around, for at least half an hour after swallowing your tablet. This is to help avoid irritation to your food pipe, or oesophagus.⁴

⁴ Alternatively, place under *While you are taking it/ Things you must not do*. Preferred location should be determined by testing.

When to take it

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

demeclocycline, methacycline, tetracycline:

Take Medicine Name on an empty stomach, either one hour before or two hours after any food.

doxycycline and minocycline:

Take Medicine Name during or immediately after a meal, at about the same time each day (usually in the morning).

If taken on an empty stomach, it may cause stomach upset.

How long to take it

Do not stop taking the tablets/capsules 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 one or two weeks.

⁵ Alternatively, place under *While you are taking it/ Things you must not do*. Preferred location to be determined by testing.

For controlling acne, Medicine Name is normally taken for a few months.

For preventing malaria, Medicine Name is normally recommended to be taken for up to a maximum of 8 weeks.

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

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

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

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 as you would normally.⁶

Do not double a 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 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

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.

urgent medical attention.⁸ Keep telephone numbers for these places handy.

If you take too much Medicine Name, you may feel ... (as per PI)

While you are taking Medicine Name

Things you must do

If you are taking Medicine Name for an infection and your symptoms do not improve within a few days, or if they become worse, tell your doctor.

If you get severe diarrhoea, tell your doctor or pharmacist 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 become pregnant while taking Medicine Name, tell your doctor immediately.

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

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

If you are taking iron preparations, including vitamin preparations containing iron, or antacids, you must take them at least two hours before or two hours after Medicine Name to

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

make sure there is no problem with absorption.⁹

Things you must not do

Do not stop taking your tablets / capsules 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 it 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.¹⁰

Things to be careful of

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.

If you get thrush (a fungal infection which can affect the mouth and / or vagina) or any other infection while taking, or soon after stopping Medicine Name, tell your doctor.

⁹ You may wish to include an additional caution about iron preparations and antacids here. The need for an extra statement should be determined by testing

¹⁰ 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".

Sometimes use of this medicine allows fungi to grow. These fungi are not killed by Medicine Name.

minocycline only:

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

Medicine Name may cause dizziness or lightheadedness in some people and therefore may affect alertness.

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 is effective against infections / acne / the prevention of malaria (include approved indications) for most people but may have unwanted side effects in some.

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.