

Core CMI for Quinolone Antibiotics (*text in italics is instructional*)

This core CMI is for both oral and parenteral dosage forms - information under "While you are using Medicine Name" may only be appropriate for the oral preparations.

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

Generic Name

Consumer Medicine Information

Name

Address

Address

What is in this leaflet¹

Standard information as suggested in the Usability Guidelines:

This leaflet answers some common questions about Medicine Name. It does not contain all of 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.

What Medicine Name is used for

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

² Consider reversing "risks" and "benefits"

Medicine Name is an antibiotic used to treat infections in different parts of the body caused by bacteria.

Alternative:

Medicine Name is an antibiotic used to treat some bacterial infections, such as:

- urinary tract infections
- *list as per PI*

If applicable:

Medicine Name is also used to prevent ...(*as per PI*)

Medicine Name will not work against infections caused by viruses, such as colds or the flu.

Optional for UTI indication :

Urinary tract infections are caused by the presence of bacteria in the urinary system. The bacteria often come from the intestines where they are necessary for normal function.

In women, the most common infection involves the bladder and is called cystitis. In men, the infection may involve the prostate which is called prostatitis. In both men and women, the bacteria may travel up to the kidneys and infect them.

The symptoms of a urinary tract infection may include an urge to urinate frequently and in small amounts, and painful burning when passing urine. If urinary tract infections persist, they should be

treated to avoid the kidneys being infected.

Mechanism of action:

Medicine Name is an antibiotic that belongs to a group of medicines called. These antibiotics work by killing the bacteria that are causing your infection (*or by stopping its growth*).

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.

Before you take Medicine Name

or

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

Before you are given Medicine Name

***When you must not take it
When you must not be given it***

Do not take/use Medicine Name if:

1. you have an allergy to:

- Medicine Name
- other quinolone antibiotics
- 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.

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

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'.

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 or to growing teenagers, unless advised by the doctor.

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

***Before you start to take it
Before you are given it***

You must tell your doctor if:

1. you have any allergies to:

- any other medicines including aspirin or other NSAID medicines
- 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 health problems/medical conditions, including:

- kidney disease
- seizures or fits or a history of them
- *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 that you buy without a prescription from your pharmacy, supermarket or health food shop.

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

- theophylline, a medicine used to treat asthma
- warfarin, a medicine used to stop blood clots
- probenecid, a medicine used to treat gout
- *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.

Norfloxacin & ciprofloxacin only:

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

- iron or zinc supplements, and multivitamins containing them
- antacids used for indigestion
- sucralfate, a medicine used to treat stomach ulcers
- *as per PI*

You can still take these medicines while you are taking/being given Medicine Name. However, you must take Medicine Name at least 2 hours before or 2 hours after taking any of these medicines to make sure there is no problem with absorption of the medicine.

Alternative:

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

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

Injection only:

How Medicine Name is given

This information will be product specific, consistent with the approved PI.

Medicine Name is given as a slow injection into a vein. Medicine Name must only be given by a doctor or nurse.

Your doctor will decide what dose and how long you will receive Medicine Name. This depends on your infection and other factors, such as your weight. For most infections, Medicine Name is usually given in divided doses throughout the day.

Oral:

How to take 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 headings and information are suggested but may not be necessary in all cases:

How much to take

Include dosages 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 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 other 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.

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

Take your Medicine Name about twelve hours apart.

Taking Medicine Name at evenly spaced times will ensure that there is a constant amount in the blood or urine. This will mean that the medicine will fight the infection more effectively.

Norfloxacin & ciprofloxacin only:

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

This will make sure the tablets will have a better chance of fighting the infection, because food can interfere with the absorption of Medicine Name.

Do not take Medicine Name at the same time as taking iron or

zinc supplements (or multivitamins containing them), antacids, or sucralfate.

Taking Medicine Name at the same time or even within two hours of taking these can interfere with the absorption of Medicine Name, so that the chance of Medicine Name fighting the infection won't be as good.

How long to take it

Continue taking Medicine Name until you finish the pack or until your doctor recommends.⁶

Do not stop taking your tablets 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 it may return.⁷

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.

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 your tablets as you would normally.⁸

⁶ Consider reversing "your doctor recommends" and "finishing pack"

⁷ Alternatively place under 'Things you must not do' - testing will determine best location.

⁸ These two sentences are in reverse order from that recommended in the Usability Guidelines.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26)⁹ 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.¹⁰ Keep telephone numbers of these places/services handy.

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

While you are using Medicine Name

Things you must do

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

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.

⁹ Consider including the relevant New Zealand telephone numbers here.

¹⁰ The reference to casualty and urgent medical attention could be left out, depending on the type of product.

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.

Drink plenty of water or fluids while taking Medicine Name.

This will help to prevent crystals forming in the urine which can cause kidney problems. However, this is not a common problem. *(if applicable)*

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

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

Tell all the 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 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 complaints unless your doctor tells you to.¹¹

Things to be careful of

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

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.

Side effects

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

¹¹ 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"

However, some may be serious and need medical attention.

Ask your doctor or pharmacist to answer any questions you may have.

While you are using Medicine Name

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

- *list as appropriate*

These are the more common side effects of Medicine Name. For the most part these have been mild.

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

- *list as appropriate*

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 appropriate*

These are very serious side effects. If you have them, you may have a serious allergic reaction to Medicine Name. You may need urgent medical attention or hospitalisation. All of these side effects are rare.

After finishing Medicine Name

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. Medicine Name can cause bacteria, which is normally present in the bowel and normally harmless, to multiply and therefore cause the above symptoms. You may need urgent medical attention. However, this side effect is rare.

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

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 using Medicine Name

Storage

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

Oral:

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

If you take the tablets 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 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 good place to store medicines.

Injections:

Medicine Name will be stored in the pharmacy or on the ward. The injection is kept in a cool dry place, protected from light, where the temperature stays below 30°C.

Oral:

Disposal

If your doctor tells you to stop taking the tablets or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets 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 (as appropriate).

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.