

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

This core CPI is for both oral and parenteral dosage forms - information under 'While you are using PRODUCT 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 Usability Guidelines.

This leaflet answers some common questions about Medicine Name, [including how to use the eye drops - *if appropriate*]. 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 using Medicine Name against the benefits they expect it will have for you.

If you have any concerns about using/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

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

Injection only:

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

² Consider reversing "risks" and "benefits"

Medicine Name is also used to prevent infections before, during and after surgery.

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

Mechanism of action:

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

Alternative mechanism for injections:

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

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.

Statement about addictive properties³:

Medicine Name is not addictive.

or

There is no evidence that Medicine Name is addictive.

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

This medicine is available only with a doctor's prescription.

Before you take Medicine Name

or

Before you are given Medicine Name

*NB. Items marked * may be included under 'Before you start to take Medicine Name' as an alternative or in addition to this section.*

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 penicillins
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing ...(*as per PI*)

2. you have had an allergic reaction to cephalosporins.

You may have an increased chance of being allergic to Medicine Name if you are allergic to cephalosporins.

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 are given it***

Tell your doctor if:

1. you have any type of allergic reaction to cephalosporin medicines

You may have an increased chance of being allergic to Medicine Name if you are allergic to cephalosporins.

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

3. you have or have ever had any other health problems / medical conditions, including:

- asthma
- kidney problems
- *as per PI*

4. you are pregnant or intend to become pregnant.

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

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

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

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:-

- *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. 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.

Alternative:

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

Talk to your doctor about the need for an additional method of 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

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

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

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/being given Medicine Name with other medicines.

Injection only:

How Medicine Name is given

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

Medicine Name can be given in two ways:

- as a slow injection into a vein
- as a deep injection into a large muscle

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.

Sometimes only a single dose of Medicine Name is required for the treatment and prevention of certain infections.

Oral - solids and liquids:

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 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

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

How long to take it

Continue taking Medicine Name until you finish the pack / bottle or until your doctor recommends.⁵

Do not stop taking your 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 it may return.⁶

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 / capsules / mixture as you would normally.⁷

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

⁵ Consider reversing "your doctor recommends" and "finishing pack/bottle"

⁶ Alternatively place under 'Things you must not do' - testing will determine best location.

⁷ These two sentences are in reverse order from that recommended in the Usability Guidelines.

Centre (telephone 13 11 26)⁸, 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 attention⁹. Keep these telephone numbers handy.

If you take too much Medicine Name you may get diarrhoea and nausea. There are unlikely to be any serious problems from an overdose of Medicine Name.

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 develop itching with swelling or skin rash or difficulty breathing while you are taking Medicine Name do not take any more and contact your doctor immediately.

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 infection called thrush. Sometimes

⁸ Consider including the relevant New Zealand telephone numbers here.

⁹ The reference to casualty and urgent medical attention could be left out, depending on the type of product.

the use of Medicine Name allows fungi to grow and the above symptoms to occur. Medicine Name does not work against fungi.

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

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

If you have to have any blood tests tell your doctor you are taking / using / being given Medicine Name.

Medicine Name may affect the results of some blood tests.

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 / 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 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.¹⁰

Things to be careful of

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

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"*

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 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 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. 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 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 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 diarrhoea medicine without first checking with your doctor.

Alternative explanation:

These are rare but serious side effects. Medicine Name can change 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.

After using Medicine Name

Oral - solids and liquids:

Storage

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

Keep your tablets in the [blister] pack until it is time to take them.

If you take the tablets out the [blister] pack they may not keep well.

Keep it 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

Storage

Medicine Name will be stored in the pharmacy or on the ward. The powder for injection is kept in a cool dry place 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

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