

**Core CMI for Cephalosporin 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<sup>®</sup> *(phonetic spelling if required)*

Generic name

## Consumer Medicine Information

Name  
Address  
Address

### What is in this leaflet<sup>1</sup>

*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 and pharmacist.

All medicines have risks and benefits<sup>2</sup>. 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

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

<sup>2</sup> Consider reversing "risks" and "benefits"

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

*Injection only:*

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 belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

*Alternative:*

Medicine Name works by killing the bacteria 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.

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

*Statement about addictive properties<sup>3</sup>:*

Medicine Name is not addictive.

<sup>3</sup> Consider using addictive statement if product is used for longterm therapy

or

There is no evidence that Medicine Name is addictive.

### Before you take Medicine Name

or

### Before you are given Medicine Name

*Some of these items 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 cephalosporins or 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 a serious allergic reaction to penicillins**

*Tampering and Expiry Date Warnings:*

**Do not use Medicine Name if the packaging is torn or shows signs of tampering.**

or

**Do not use Medicine Name after 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, have no effect at all, or worse, have an unexpected effect.<sup>4</sup>

**If you are not sure whether you should start taking Medicine Name, contact 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 penicillin medicines**

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

**2. you have any allergies to:**

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

*Pregnancy and breast-feeding*<sup>5</sup>:

**1. you are pregnant, or intend to become pregnant.**

Medicine Name may affect your developing baby if you take it during pregnancy.

**2. 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.

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<sup>4</sup> Expiry date and torn packaging warnings may not be appropriate for parenteral preparations

<sup>5</sup> Consider including pregnancy and breast-feeding statements here or under 'Before you start to take it'.

**3. if you have or have had any medical conditions, including:**

- kidney disease
- severe bowel conditions/disease
- 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:-

- list as per PI

These medicines may be affected by Medicine Name, or may affect how well it works. You may need to take 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 Medicine Name.**

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with Medicine Name.<sup>6</sup>

Your doctor and pharmacist may have 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:*

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<sup>6</sup> This is recommended text from QARG for the potential for interaction between antibiotics and oral contraceptives.

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## How Medicine Name is given

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*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:*

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## How to take Medicine Name

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*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 subheadings and information 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.*

**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.**

### **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.<sup>7</sup>

**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.<sup>8</sup>

*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**

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<sup>7</sup> Consider reversing "your doctor recommends" and "finishing pack/bottle"

<sup>8</sup> Alternatively place under 'Things you must not do' - testing will determine best location.

*(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.<sup>9</sup>**

**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)<sup>10</sup>, 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 attention<sup>11</sup>. Keep these telephone numbers handy.**

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

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## **While you are using Medicine Name**

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### **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.**

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<sup>9</sup> These two sentences are in reverse order from that recommended in the Usability Guidelines.

<sup>10</sup> Consider including the relevant New Zealand telephone numbers here.

<sup>11</sup> The reference to casualty and urgent medical attention could be left out, depending on the type of product.

**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 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 immediately.**

**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 test your urine for sugar while you are using/being given Medicine Name, make sure your doctor knows which type of test you use.**

Medicine Name may affect the results of some of these tests.

**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.

*For cefotetan, cephamandole only:*

**Do not drink any alcohol while you are being given Medicine Name and for at least 5 days after stopping Medicine Name. This includes any other alcohol-containing preparations, such as some cough mixtures.**

If you drink alcohol you may experience flushing, sweating, headache or a fast heart rate. Check with your doctor or pharmacist to make sure you are not taking any other medicines which contain alcohol.

**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.**<sup>12</sup>

### **Things to be careful of**

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

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.

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## **Side effects**

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*(Only the opening general statements will be consistent in this section. Other statements will be*

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<sup>12</sup> 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 PRODUCT NAME"

*product specific and consistent with Pl.)*

**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.**

### **While taking Medicine Name**

**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 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 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. You may need urgent medical attention or hospitalisation. 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. 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:*

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

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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

*or*

Some people may get other side effects while taking/using/being given Medicine Name.

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

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## After using Medicine Name

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*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 of the [blister] pack they may not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 30°C. 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 Medicine Name 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:*

### **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.**

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## Product description

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*(This information will be product specific. The Usability Guidelines suggest the information should be presented in the following order:)*

### **What it looks like**

### **Ingredients**

*Include as appropriate:*

Medicine Name does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

*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 CMI. In order to achieve consistency, however, CMI writers are encouraged to use these statements and follow the Usability Guidelines wherever possible.***