

## Cefotaxime Sandoz®

cefotaxime sodium powder for injection

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Cefotaxime Sandoz.

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 benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

#### Keep this leaflet.

You may need to read it again.

#### What Cefotaxime Sandoz is used for

This medicine is used to treat infections in different parts of the body caused by bacteria.

Cefotaxime Sandoz is also used to prevent infections before, during and after surgery.

It contains the active ingredient cefotaxime sodium.

Cefotaxime belongs to a group of medicines called cephalosporin antibiotics.

It works by killing bacteria that are causing your infection.

#### Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

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

#### Before you are given Cefotaxime Sandoz

##### When you must not be given it

##### Do not use this medicine if you have an allergy to:

- cefotaxime, the active ingredient
- any other similar medicines such as cephalosporins.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

##### Do not use this medicine if you have or have had a serious allergic reaction to any penicillins.

You may be more likely to have an allergic reaction to Cefotaxime Sandoz if you are allergic to penicillin medicines.

##### Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

##### Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- any type of allergic reaction to any cephalosporin or penicillin medicines. You may have an increased chance of being allergic to Cefotaxime Sandoz if you are allergic to any cephalosporins or penicillins.
- allergies to lignocaine or other local anaesthetics. Lignocaine may be mixed with Cefotaxime Sandoz prior to injection.
- kidney problems
- heart problems
- liver problems
- stomach or bowel problems
- asthma.

##### Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

##### If you have not told your doctor about any of the above, tell him/her before you are given Cefotaxime Sandoz.

##### Taking other medicines

##### Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Cefotaxime Sandoz may interfere with each other. These include:

- aminoglycoside antibiotics, including gentamicin
- bacteriostatic antibiotic medicines such as tetracyclines, erythromycin and chloramphenicol
- fluid tablets or diuretic medicines such as frusemide
- probenecid, a medicine used to treat gout
- oral contraceptive medicines (birth control medicines).

These medicines may be affected by Cefotaxime Sandoz or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

##### Talk to your doctor about the need for an additional method of contraception while being treated with Cefotaxime Sandoz.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

#### How Cefotaxime Sandoz is given

##### How much is given

##### Your doctor will decide what dose and how long you will receive Cefotaxime Sandoz.

This depends on your condition and whether you are using other medicines.

For most infections, Cefotaxime Sandoz is usually given in divided doses throughout the day.

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

##### How it is given

Cefotaxime Sandoz must only be given by a doctor or nurse.

It is reconstituted before being injected.

Cefotaxime Sandoz can be given in two ways:

- as a slow injection into a vein

- as a deep injection into a large muscle.

##### If you take too much (overdose)

As Cefotaxime Sandoz is given to you under the supervision of your doctor, it is unlikely that you will receive too much.

##### Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else are experiencing severe side effects after being given Cefotaxime Sandoz.

You may need urgent medical attention.

If you are given too much Cefotaxime Sandoz you may experience symptoms such as:

- stomach upsets
- headache
- dizziness
- seizures.

#### While you are given Cefotaxime Sandoz

##### Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Cefotaxime Sandoz.

Tell any other doctors, dentists, and pharmacists who treat you that you are being treated with this medicine.

If you become pregnant while you are being treated with this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are being treated with this medicine.

It may interfere with the results of some tests.

If you have to test your urine for sugar while you are being treated with this medicine, make sure your doctor knows which type of test you use.

Cefotaxime Sandoz may affect the results of some of these tests.

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

If you experience severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Cefotaxime Sandoz 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 being treated with or soon after stopping Cefotaxime Sandoz, tell your doctor. Also tell your doctor if you experience vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Sometimes the use of Cefotaxime Sandoz allows fungi to grow and the above symptoms to occur. Cefotaxime Sandoz does not work against fungi.

### Things to be careful of

#### **Be careful driving or operating machinery until you know how Cefotaxime Sandoz affects you.**

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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### Side effects

#### **Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are being treated with Cefotaxime Sandoz.**

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

#### **Do not be alarmed by the following lists of side effects. You may not experience any of them.**

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

#### *While you are given Cefotaxime Sandoz*

**Tell your doctor, nurse or pharmacist 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, sometimes with a white discharge
- pain or swelling at the injection site
- diarrhoea
- nausea (feeling sick) or vomiting
- headache or dizziness.

These are usually mild side effects of the medicine.

#### **If any of the following happen, tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital:**

- severe abdominal or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing or difficulty breathing
- skin rash, itching, hives, blisters or peeling skin
- fast or irregular heart beat
- signs of frequent infections such as fever, sore throat, swollen glands or mouth ulcers
- unusual bleeding or bruising under the skin
- signs of anaemia, such as tiredness, headache, dizziness, being short of breath when exercising or looking pale
- yellowing of the skin or eyes, also known as jaundice
- blood in the urine
- seizures or abnormal movements.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

#### *After being given Cefotaxime Sandoz*

**Tell your doctor immediately if you notice any of the following side effects, even if they occur several weeks after stopping treatment with Cefotaxime Sandoz:**

- severe abdominal or stomach cramps
- watery and severe diarrhoea, which may 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.

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

#### **Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

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### After being given Cefotaxime Sandoz

#### *Storage*

This medicine will be stored in the hospital pharmacy or on the ward and will be looked after by your doctor or pharmacist.

Vials of Cefotaxime Sandoz Powder for Injection should be kept in a cool dry place, protected from heat and light, where the temperature stays below 25°C.

The reconstituted solution must be used immediately and any unused solution should be discarded.

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### Product description

#### *What it looks like*

Cefotaxime Sandoz comes in three types of vials:

- Cefotaxime Sandoz 0.5g - white to slightly yellow powder.
- Cefotaxime Sandoz 1g - white to slightly yellow powder.
- Cefotaxime Sandoz 2g - white to slightly yellow powder.

Available in cartons of 1 vial.

#### *Ingredients*

- Cefotaxime Sandoz 0.5g - 0.5g cefotaxime, as cefotaxime sodium
- Cefotaxime Sandoz 1g - 1g cefotaxime, as cefotaxime sodium
- Cefotaxime Sandoz 2g - 2g cefotaxime, as cefotaxime sodium

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

#### *Supplier*

Cefotaxime Sandoz is supplied in Australia by:

**Sandoz Pty Ltd**  
ABN 60 075 449 553  
19 Harris Street  
Pymont NSW 2009  
Australia  
Tel: 1800 634 500

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#### **Australian Register Numbers**

0.5g powder for injection: AUST R 76431  
1g powder for injection: AUST R 76432  
2g powder for injection: AUST R 76433