CEFAZOLIN SANDOZ®

Cephazolin sodium powder for injection

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Cefazolin 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 using Cefazolin Sandoz against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

WHAT CEFAZOLIN SANDOZ IS USED FOR

The name of your medicine is Cefazolin Sandoz. It contains the active ingredient cephazolin sodium.

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

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

Your doctor may have prescribed Cefazolin Sandoz for another reason.

Ask your doctor if you have any questions about why Cefazolin Sandoz has been prescribed for you.

Cefazolin Sandoz is available only with a doctor's prescription. It is not addictive.

BEFORE YOU ARE GIVEN CEFAZOLIN SANDOZ

When you must not be given Cefazolin Sandoz

Do not use Cefazolin Sandoz if:

1. you have an allergy to the active ingredient, cephazolin sodium, or to any other cephalosporins

Some of the symptoms of an allergic reaction may include asthma, wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, skin rash, itching or hives.

2. you have had a serious allergic reaction to any penicillins.

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

Do not use Cefazolin Sandoz if the packaging is torn or shows signs of tampering.

Do not use Cefazolin Sandoz after the expiry date on the pack has passed. If you are not sure whether you should be given Cefazolin Sandoz, talk to your doctor or nurse.

Before you are given Cefazolin Sandoz

Tell your doctor if:

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

You may have an increased chance of being allergic to Cefazolin Sandoz if you are allergic to any cephalosporins or penicillins.

- 2. you have any allergies to:
- any other medicines
- any other substances, such as foods, preservatives or dyes.
- 3. you are pregnant, or intend to become pregnant

Cefazolin Sandoz may affect your developing baby if you use it during pregnancy. Your doctor will discuss the risks and benefits of using Cefazolin Sandoz during pregnancy.

4. you are breast-feeding or intend to breast-feed

Cefazolin Sandoz passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using Cefazolin Sandoz when breastfeeding.

- 5. if you have or have had any medical conditions, including:
- · kidney disease
- stomach or bowel problems.

If you have not told your doctor about any of the above, tell them before you are given Cefazolin Sandoz.

Use in Children

Cefazolin Sandoz is not recommended for use in premature infants or infants under one month of age. The safety of Cefazolin Sandoz in premature infants and infants under one month of age has not been established.

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 Cefazolin Sandoz. These include:

- probenecid, a medicine used to treat gout
- warfarin, a medicine used to prevent blood clots
- other antibiotics such as amikacin, gentamicin, tobramycin
- typhoid vaccine.

These medicines may be affected by Cefazolin Sandoz, or may affect how well it works. You may need to use different amounts of your medicine, or you may need to use different medicines. Your doctor will advise you.

Talk to your doctor about the need for an additional method of contraception while using Cefazolin Sandoz.

Some antibiotics may decrease the effectiveness of some birth control pills.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using Cefazolin Sandoz.

HOW CEFAZOLIN SANDOZ IS GIVEN

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

Cefazolin Sandoz can be given:

• into a vein via a drip

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

Your doctor will decide what dose and how long you will receive Cefazolin Sandoz. This depends on your condition and whether you are taking any other medicines. For most infections, Cefazolin Sandoz is usually given in divided doses throughout the day.

Sometimes only a single dose of Cefazolin Sandoz is required for the treatment of certain infections.

If you are given too much (overdose)

In the unlikely event of an overdose, your treating physician will know what to do.

If you are given too much Cefazolin Sandoz you may experience redness, pain or inflammation where the injection was given, stomach upset, headaches, chills, dizziness, tingling or numbness of the hands and feet or seizures.

WHILE YOU ARE USING CEFAZOLIN SANDOZ

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 get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Cefazolin 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 using or soon after stopping Cefazolin Sandoz, 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 Cefazolin Sandoz allows fungi to grow and the above symptoms to occur. Cefazolin Sandoz does not work against fungi.

If you become pregnant while you are using Cefazolin Sandoz, tell your doctor immediately.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are using Cefazolin Sandoz.

If you have to test your urine for sugar while you are being given Cefazolin Sandoz, make sure your doctor knows which type of test you use.

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

Tell all the doctors, dentists and pharmacists who are treating you that you are using Cefazolin Sandoz.

Things to be careful of

Be careful driving or operating machinery until you know how Cefazolin Sandoz affects you.

Cefazolin Sandoz may cause dizziness in some people. Make sure you know how you react to Cefazolin Sandoz before you drive a car, operate machinery or do anything else that may be dangerous if you are affected.

SIDE EFFECTS

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well after you are given Cefazolin Sandoz.

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.

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

While using Cefazolin Sandoz

Tell your doctor or nurse 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
- diarrhoea
- nausea or vomiting
- pain, redness and swelling where the injection was given.

These are the more common side effects of Cefazolin Sandoz. These side effects are usually mild.

Tell your doctor or nurse immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody
- fever
- skin rash, itching or hives
- swelling of the face, lips or tongue which may cause difficulty swallowing or breathing
- wheezing or shortness of breath
- bleeding or bruising more easily than normal
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

These are serious side effects. You may need urgent medical attention. These serious side effects are rare.

After finishing Cefazolin Sandoz

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

- 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.

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

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.

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

Tell your doctor if you notice anything else that is making you fell unwell.

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

AFTER USING CEFAZOLIN SANDOZ

Storage

Cefazolin Sandoz will be stored in the pharmacy or on the ward.

The powder for injection is kept in a cool, dry place, protected from light and moisture, where the temperature stays below 25°C.

PRODUCT DESCRIPTION

What it looks like

Cefazolin Sandoz is a white to offwhite powder. It is reconstituted before being injected.

Ingredients

Active ingredient:

Each vial contains 1 g and each infusion bottle 2 g of cephazolin, as the sodium salt.

Cefazolin Sandoz does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

Supplier

Sandoz Pty Ltd

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Australian Registration Numbers

- Vials
 - 1 g AUST R 75956
- Infusion bottles

2 g - AUST R 97685