

Cefaclor Sandoz[®]

Cefaclor (as monohydrate)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

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

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

WHAT CEFACLOR SANDOZ IS USED FOR

The name of your medicine is Cefaclor Sandoz. It contains the active ingredient cefaclor monohydrate.

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

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

Cefaclor Sandoz will not work against infections caused by viruses such as colds or the flu.

Your doctor may have prescribed Cefaclor Sandoz for another reason. Ask your doctor if you have any questions about why Cefaclor Sandoz has been prescribed for you.

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

This medicine is not addictive.

BEFORE YOU TAKE CEFACLOR SANDOZ

When you must not take it

Do not take Cefaclor Sandoz if you have an allergy to:

- **Cefaclor any other cephalosporins or any of the ingredients listed at the end of this leaflet under Product Description.**
- **Any other similar medicines**

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips or tongue or other parts of the body which may cause difficulty in swallowing or breathing
- skin rash, itching or hives.

Do not take this medicine if you have or have had any of the following medical conditions:

- **a serious allergic reaction to any penicillins.** You may be more likely to have an allergic reaction to Cefaclor Sandoz if you are allergic to penicillin medicines.

Do not give Cefaclor Sandoz to a premature baby or to a baby less than one month old.

The safety and effectiveness of Cefaclor Sandoz have not been established in this age group.

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

medicine does not look quite right.

Do not use Cefaclor Sandoz after the expiry date printed on the pack has passed.

If you are not sure whether you should start taking Cefaclor Sandoz, contact your doctor.

Before you start to take it

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

- **Type of allergic reaction to any penicillin medicines.** You may have an increased chance of being allergic to Cefaclor Sandoz if you are allergic to penicillins.
- **you have any allergies to any other medicines any other substances, such as foods, preservatives or dyes**
- **kidney problems**
- **stomach or bowel problems**
- **liver problems.**

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

Your doctor can discuss the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you take Cefaclor Sandoz.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines that you buy without

a prescription from your pharmacy, supermarket or health food shop.

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

- probenecid, a medicine used to treat gout
- oral anticoagulants.

These medicines may be affected by Cefaclor Sandoz, 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 Cefaclor 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 taking Cefaclor Sandoz.

HOW TO TAKE CEFACLOR SANDOZ

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will tell you how much Cefaclor Sandoz you need to take. This will depend on the type of infection you have.

Adults

The usual dose of Cefaclor Sandoz is 250mg every 8 to 12 hours. This dose may vary depending on your condition.

Children

The dose for children varies according to the age of the child, their weight and the type of infection. Your doctor and pharmacist will tell you the right amount to give your child.

How to take it

Cefaclor Sandoz capsules are taken orally.

When to take it

Cefaclor Sandoz can be taken with or without food.

How long to take it

Continue taking this medicine for as long as your doctor tells you. Keep taking this medicine for the full course 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

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone New Zealand 0800 POISON or 0800 764766)

for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Cefaclor Sandoz. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include symptoms such as feeling sick in the stomach, vomiting or diarrhoea.

WHILE YOU ARE USING CEFACLOR 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 or pharmacist immediately. Do this even if it occurs several weeks after Cefaclor 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 taking or soon after stopping Cefaclor 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 Cefaclor Sandoz allows fungi to grow and the above symptoms to occur. Cefaclor Sandoz does not work against fungi.

If you become pregnant while you are taking Cefaclor Sandoz tell your doctor immediately.

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

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

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

If you have to have any blood tests tell your doctor you are taking Cefaclor Sandoz.

Cefaclor Sandoz may affect the results of some blood tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Cefaclor Sandoz.

Things you must not do

Do not stop taking your Cefaclor Sandoz 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 Cefaclor Sandoz to anyone else, even if they have the same condition as you.

Do not use Cefaclor Sandoz to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

Cefaclor Sandoz may cause drowsiness and dizziness in some people. Make sure you know how you react to Cefaclor Sandoz before you drive a car, operate machinery or do anything else that may be dangerous if you are affected. Children should be careful when riding bicycles or climbing trees.

SIDE EFFECTS

Tell your doctor or pharmacist

as soon as possible if you do not feel well while you are taking Cefaclor 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 taking Cefaclor Sandoz

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
- mild diarrhoea
- feeling sick, vomiting
- dizziness, drowsiness
- headache
- nervousness, hyperactivity
- inability to sleep.

These side effects are usually mild.

If any of the following happen, stop taking Cefaclor Sandoz and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- severe abdominal cramps or stomach cramps
- watery and severe diarrhoea, which may also be bloody or contain mucus
- rash, itching, severe body rash with pinkish, itchy swellings of the skin (hives), blistering or peeling of the skin
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers
- pain or swelling of the joints
- yellowing of the skin or eyes
- shortness of breath, wheezing or difficulty in breathing
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing

- severe blisters and bleeding of the lips, eyes, mouth, nose and genitals
- unusual muscle stiffness causing poor control of movement
- confusion, hallucinations
- kidney pain, blood in the urine, passing more or less urine than is normal for you.

These are very serious side effects. You may need urgent medical attention or hospitalisation. Serious side effects are rare.

After taking Cefaclor Sandoz

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Cefaclor 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.

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.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything making you feel unwell.

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

AFTER USING CEFACLOR SANDOZ

Storage

Keep Cefaclor Sandoz where children cannot reach it.

Capsules

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

Keep your medicine in a cool dry place where the temperature stays below 30°C.

Do not store Cefaclor Sandoz or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in a car.

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 a good place to store medicines.

Disposal

If your doctor tells you to stop taking Cefaclor Sandoz or you find that the medicine has passed the expiry date, ask your pharmacist what to do with any medicine that is left over.

PRODUCT DESCRIPTION

What it looks like

Cefaclor Sandoz 250mg capsules - reddish brown opaque cap and body. Each capsule contains cefaclor monohydrate equivalent to cefaclor 250mg.

*Cefaclor Sandoz 500mg capsules- reddish brown opaque cap and body. Each capsule contains cefaclor monohydrate equivalent to cefaclor 500mg.

*Not marketed.

Ingredients

Cefaclor Sandoz 250mg capsules contains 250mg cefaclor (as monohydrate) as the active ingredient.

Cefaclor Sandoz 500mg capsules contains 500mg cefaclor (as monohydrate) as the active ingredient. – Not marketed.

It contains the following inactive ingredients:

- Gelatin
- Croscarmellose sodium
- Dimethicone
- Magnesium stearate
- Iron oxide red
- Titanium dioxide

SUPPLIER:

Novartis New Zealand Ltd
Private Bag 65904 Mairangi Bay
Auckland 0754
New Zealand
Tel: 0800 354 335

This leaflet was prepared in August 2010.