

CEFALEXIN SANDOZ®

Cephalexin Monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Cefalexin Sandoz.

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. Your doctor has weighed the risks of you taking Cefalexin 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.

Keep this leaflet with the medicine.

You may need to read it again.

What Cefalexin Sandoz is used for

The name of your medicine is Cefalexin Sandoz. It contains the active ingredient cephalexin monohydrate.

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

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

Cefalexin Sandoz can be used to treat infections of the:

- respiratory tract (throat, tonsils, chest and lungs)
- nose (sinusitis)
- ears (otitis media)
- skin and soft tissue

- kidneys and bladder (genitourinary tract).

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

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

Before you take Cefalexin Sandoz

When you must not take it

Do not take Cefalexin Sandoz if:

1. **you have an allergy to cephalexin monohydrate, other cephalosporins or any of the ingredients listed at the end of this leaflet.**
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 Cefalexin Sandoz if you are allergic to any penicillins.

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

Do not use Cefalexin Sandoz after the expiry date printed on the bottle or carton has passed.

If you are not sure whether you should start taking Cefalexin Sandoz, contact your doctor or pharmacist.

Before you start to take it

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 Cefalexin 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.**
Cefalexin Sandoz may affect your developing baby if you take it during pregnancy. Your doctor will discuss the risks and benefits of using Cefalexin Sandoz during pregnancy.
4. **you are breastfeeding or intend to breastfeed.**
Cefalexin Sandoz passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of using Cefalexin Sandoz when breastfeeding.
5. **you have or have had any medical conditions, including:**
 - kidney disease
 - stomach or bowel problems
 - liver disease.

If you have not told your doctor about any of the above, tell them before you start taking Cefalexin Sandoz.

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 Cefalexin Sandoz. These include:

- probenecid, a medicine used to treat gout
- metformin, a medicine used to treat diabetes.

These medicines may be affected by Cefalexin 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 taking Cefalexin 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 Cefalexin Sandoz.

How to take Cefalexin Sandoz

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

These directions 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

Cefalexin Sandoz is available as 250mg and 500mg capsules as well as 125mg/5mL and 250mg/5mL suspensions.

Adults

The usual adult dose is 250mg every 6 hours. Your doctor may

recommend a different dose depending on your condition.

Children

Your child's doctor will tell you how much Cefalexin Sandoz your child should take. This will depend on your child's age, weight and the type of infection.

How to take it

Capsule

Swallow Cefalexin Sandoz capsules with a glass of water.

Suspension

Always shake the bottle before measuring the correct volume to give to your child.

When to take it

Take each dose of Cefalexin Sandoz at about the same time each day.

Taking each dose of Cefalexin Sandoz at the same time each day will have the best effect. It will also help you to remember when to take the medicine.

It does not matter if you take Cefalexin Sandoz before or after food.

How long to take it

Continue taking Cefalexin Sandoz until you finish the pack or until your doctor recommends.

If you forget to take it

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 Cefalexin Sandoz as you would normally.

Do not take a double dose to make up for the dose that you missed.

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 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much Cefalexin Sandoz. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep these telephone numbers handy.

If you take too much Cefalexin Sandoz you may feel sick in the stomach, experience diarrhoea, convulsions or hallucinations.

While you are using Cefalexin 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 Cefalexin 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 Cefalexin 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 Cefalexin Sandoz allows fungi to grow and the above symptoms to occur. Cefalexin

Sandoz does not work against fungi.

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

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

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

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

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

Cefalexin Sandoz may affect the results of some blood tests.

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

Things you must not do

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

Do not use Cefalexin 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 Cefalexin Sandoz affects you.

Cefalexin Sandoz may cause tiredness or dizziness in some people. Make sure you know how you react to Cefalexin Sandoz before you drive a car or do

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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 Cefalexin 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 Cefalexin Sandoz

Tell your doctor if you notice any of the following and they worry you:

- vaginal thrush - sore and itchy vagina and/or discharge
- oral thrush – white, furry, sore tongue and mouth
- itching of the genital area and the skin around the back passage
- indigestion, stomach pain or discomfort
- diarrhoea, nausea, vomiting
- dizziness, unusual tiredness or weakness
- headache
- agitation, confusion
- painful, swollen joints.

These side effects are usually mild.

Tell your doctor immediately if you notice any of the following:

- confusion and hallucinations (seeing, feeling or hearing things that are not there)
- yellowing of the skin and eyes
- dark coloured urine
- fever
- bleeding or bruising more easily than normal.

These are serious side effects. You may need urgent medical

attention. Serious side effects are rare.

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

- watery and severe diarrhoea, which may also be bloody
- severe abdominal cramps or stomach cramps
- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing
- any skin rash, itching, hives, blistering or peeling of the skin
- severe blisters and bleeding in the lips, eyes, mouth, nose and genitals
- blood in the urine.

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

After finishing Cefalexin Sandoz

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after you stop taking Cefalexin 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 serious side effects. You may have a serious condition affecting your bowel. You may need urgent medical attention. However, these side effects are 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 else that is making you feel unwell.

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

After using Cefalexin Sandoz

Storage

Capsule

Keep your capsules in the original pack until it is time to take them. If you take your capsules out of the blister pack, they will not keep as well.

Keep your 250mg capsules in a cool dry place where the temperature stays below 30°C.

Keep your 500mg capsules in a cool dry place where the temperature stays below 25°C.

Suspension

Keep your suspension refrigerated (do not freeze). If you take the suspension out of the refrigerator, it will not keep well.

Do not use any suspension that is left in the bottle after 14 days.

Do not store Cefalexin Sandoz or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill. Heat and dampness can destroy some medicines.

Keep Cefalexin Sandoz 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 Cefalexin Sandoz, or the capsules have passed their expiry date or more than 14 days have passed since the suspension was mixed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Cefalexin Sandoz comes as capsules and suspensions.

Cefalexin Sandoz 250mg capsules have a dark green cap imprinted with "250" in black ink and a white body. Cefalexin Sandoz 500mg capsules are opaque white in colour. Each pack contains 20 capsules.

Cefalexin Sandoz 125mg/5mL and 250mg/5mL suspensions are orange-yellow in colour with a fruity flavour. Each bottle contains 100mL.

Ingredients

Capsule

Cefalexin Sandoz capsules contain cephalexin (as monohydrate) equivalent to 250mg or 500mg of cephalexin anhydrous as the active ingredient.

The 250mg capsule also contains microcrystalline cellulose and magnesium stearate. The capsule shell and body contain gelatin, sodium lauryl sulphate, titanium dioxide, sunset yellow FCF, patent blue V, quinoline yellow, TekPrint SW-9008 black ink and water.

The 500mg capsule also contains magnesium stearate and microcrystalline cellulose. The capsule shell contains gelatin and titanium dioxide.

Suspension

Cefalexin Sandoz suspension contains cephalexin (as monohydrate) equivalent to 125mg/5mL or 250mg/5mL of cephalexin anhydrous as the active ingredient.

It also contains saccharin sodium, simethicone, citric acid anhydrous, guar galactomannan, sodium benzoate, sucrose, iron oxide yellow, strawberry, apple, raspberry and tutti frutti flavourings.

Sponsor

Australia
Sandoz Pty Ltd
100 Pacific Highway
North Sydney, NSW 2060
Tel: 1800 726 369

New Zealand
Sandoz New Zealand Limited
12 Madden Street
Auckland 1010
New Zealand
Tel: 0800 726 369

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Australian Register Numbers

Capsules

250mg	AUST R 150170
500mg	AUST R 78980

Suspension

125mg/5mL	AUST R 78981
250mg/5mL	AUST R 78982