

Cefalexin Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Cefalexin Sandoz?

Cefalexin Sandoz contains the active ingredient cefalexin monohydrate. Cefalexin Sandoz is used to treat infections caused by bacteria in different parts of the body, including infections of the respiratory tract (throat, tonsils, chest and lungs), nose (sinusitis), ears (otitis media), skin and soft tissue, kidneys and bladder (genitourinary tract).

For more information, see Section [1. Why am I using Cefalexin Sandoz?](#) in the full CMI.

2. What should I know before I use Cefalexin Sandoz?

Do not use if you have ever had an allergic reaction to cefalexin monohydrate, penicillin, other cephalosporins or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Cefalexin Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Cefalexin Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Cefalexin Sandoz?

- Follow all directions given to you by your doctor or pharmacist.
- You doctor will tell you how much and how often you should take Cefalexin Sandoz.

More instructions can be found in Section [4. How do I use Cefalexin Sandoz?](#) in the full CMI.

5. What should I know while using Cefalexin Sandoz?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if the symptoms of your infection do not improve within few days or if they become worse.• Remind any doctor, dentist or pharmacist you visit that you are taking Cefalexin Sandoz, especially if you are about to be started on any new medicines.• Tell your doctor if you become pregnant while taking Cefalexin Sandoz.• If you are about to have any blood tests, tell your doctor that you are taking Cefalexin Sandoz.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly or change the dosage unless your doctor tells you to.• Do not take Cefalexin Sandoz to treat any other complaints unless your doctor tells you to.• Do not give your medicine to anyone else, even if they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Cefalexin Sandoz may cause dizziness or drowsiness in some people.• Be careful driving or operating machinery until you know how Cefalexin Sandoz affects you.• Children should be careful when riding bicycles or climbing trees.
Looking after your medicine	<ul style="list-style-type: none">• Cefalexin Sandoz capsules: store below 25°C.• Cefalexin Sandoz suspension: store between 2-8°C. Refrigerate. Do not freeze. Shake well before use and discard after 14 days.

For more information, see Section [5. What should I know while using Cefalexin Sandoz?](#) in the full CMI.

6. Are there any side effects?

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Cefalexin Sandoz®

Active ingredient(s): *cefalexin monohydrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Cefalexin Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Cefalexin Sandoz.**

Where to find information in this leaflet:

- [1. Why am I using Cefalexin Sandoz?](#)
- [2. What should I know before I use Cefalexin Sandoz?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Cefalexin Sandoz?](#)
- [5. What should I know while using Cefalexin Sandoz?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Cefalexin Sandoz?

Cefalexin Sandoz contains the active ingredient cefalexin monohydrate. This medicine belongs to a group of medicines called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

Cefalexin Sandoz is used to treat infections caused by bacteria in different parts of the body, including infections of the:

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

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

Your doctor may have prescribed it for another reason.

There is no evidence that it is addictive.

2. What should I know before I use Cefalexin Sandoz?

Warnings

Do not use Cefalexin Sandoz if:

- you are allergic to cefalexin monohydrate, penicillin, other cephalosporins, or any of the ingredients listed at the end of this leaflet.
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.
Always check the ingredients to make sure you can use this medicine.
- the expiry date (EXP) on the pack has passed.
- the packaging is torn or shows signs of tampering.

Do not take Cefalexin Sandoz suspension if it has been in your refrigerator for longer than two weeks.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- are allergic to any other medicines or any foods, preservatives or dyes.
- have any other medical conditions including:
 - liver disease
 - kidney disease
 - bowel disease.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Talk to your doctor if you are pregnant or intend to become pregnant or are breastfeeding.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with Cefalexin Sandoz and affect how it works.

These include:

- probenecid (e.g. Pro-Cid), a medicine commonly used to treat gout
- metformin, a medicine used in the treatment of diabetes.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Cefalexin Sandoz.

4. How do I use Cefalexin Sandoz?

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

These directions may differ from the information contained in this leaflet.

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

Your Pharmacist will make up the suspension in the bottle, before giving it to you.

FOR PHARMACIST ONLY - Instructions for reconstitution:

Cefalexin Sandoz 125 mg/5mL oral suspension: Invert bottle and tap to loosen granules. Add 64 mL of water to granules in the bottle. Close and shake well at once.

Cefalexin Sandoz 250 mg/5mL oral suspension: Invert bottle and tap to loosen granules. Add 63 mL of water to granules in the bottle. Close and shake well at once.

How much to take

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

Adults

The usual adult dose is 500 mg 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 Cefalexin Sandoz

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 Cefalexin Sandoz

- 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 Cefalexin Sandoz

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

If you forget to use Cefalexin Sandoz

Cefalexin Sandoz should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking your medicine 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 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 use too much Cefalexin Sandoz

If you think that you have used too much Cefalexin Sandoz, you may need urgent medical attention.

Symptoms of an overdose may include feeling sick in the stomach, diarrhoea, blood in the urine, unusually increased reflexes, convulsions or hallucinations.

You should immediately:

- phone the Australian Poisons Information Centre (by calling 13 11 26), or the New Zealand National Poisons Information Centre (by calling 0800 POISONS or 0800 764 766), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Cefalexin Sandoz?

Things you should do

- Tell your doctor if the symptoms of your infection do not improve within a few days or if they become worse.
- Tell any other doctors, dentists and pharmacists who are treating you that you are taking Cefalexin Sandoz, especially if you are about to be started on any new medicines.
- Tell your doctor if you become pregnant while taking this medicine.
- If you are about to have any blood tests, tell your doctor that you are taking Cefalexin Sandoz. It may interfere with the results of some tests.
- If you are diabetic, check with your doctor or pharmacist before using urine sugar tests. Cefalexin Sandoz may affect the results of some of these tests.
- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you should not do

- Do not stop using this medicine suddenly or change the dosage without first checking with your doctor. If you stop taking it, your condition may worsen.

- Do not take Cefalexin Sandoz to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Cefalexin Sandoz affects you.

It may cause dizziness in some people.

Children should be careful when riding bicycles or climbing trees.

Looking after your medicine

Cefalexin Sandoz capsules

- Keep the capsules in the blister 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 capsules in a cool dry place where the temperature stays below 25°C.

Cefalexin Sandoz suspension

- Keep your suspension refrigerated (do not freeze). If you take the suspension out of the refrigerator, it will not keep well.
- Keep the bottle tightly closed.
- Do not use any suspension that is left in the bottle after 14 days.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

When to discard your medicine

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.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Common side effects

Common side effects	What to do
<ul style="list-style-type: none"> • sore or white mouth or tongue (oral thrush) • sore and itchy vagina and/or discharge (another form of thrush) • diarrhoea • nausea • vomiting • dizziness • unusual tiredness/weakness • abdominal pain • headache 	<p>Speak to your doctor if you have any of these common side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • fever • joint pain • swelling of the joints • yellowing of the skin or eyes • confusion and hallucinations • seizure • encephalopathy (such as reduced ability to think clearly or concentrate, memory loss, drowsiness, seizures, muscle twitches and personality change) • myoclonus • bleeding or bruising more easily than normal <p>Allergic reactions:</p> <ul style="list-style-type: none"> • rash, itching or hives on the skin • swelling of the face, lips, tongue or other parts of the body • shortness of breath, wheezing or trouble breathing. 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor immediately if you notice any of the following, particularly if they occur several weeks after stopping treatment with Cefalexin Sandoz:

- severe stomach cramps or pain
- severe, watery or bloody diarrhoea
- fever, in combination with one of the above.

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

You may have a serious condition affecting your bowel requiring urgent medical attention.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems or to Medsafe at pophealth.my.site.com/carmreportnz/s/. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Cefalexin Sandoz contains

Cefalexin Sandoz capsules:

Active ingredient (main ingredient)	cefalexin monohydrate (equivalent to 500 mg of cefalexin)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">magnesium stearatemicrocrystalline cellulose <p><u>Capsule shell:</u></p> <ul style="list-style-type: none">gelatintitanium dioxide

Cefalexin Sandoz capsules does not contain lactose, sucrose, gluten, tartrazine or azo dyes.

Cefalexin Sandoz suspension:

Active ingredient (main ingredient)	cefalexin monohydrate (125 mg/5 mL or 250 mg/5 mL)
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">lactosesaccharin sodiumsimethiconecitric acidguar galactomannansodium benzoatesucroseiron oxide yellowstrawberry, apple, raspberry and tutti frutti flavourings

Do not take this medicine if you are allergic to any of these ingredients.

What Cefalexin Sandoz looks like

Cefalexin Sandoz capsules:

Cefalexin Sandoz 500 mg capsules are opaque white in colour. Each pack contains 20 capsules (AUST R 78980).

Cefalexin Sandoz suspension:

Your pharmacist will make up the medicine in the bottle before dispensing it to you. Cefalexin Sandoz suspensions

are orange-yellow in colour with a fruity flavour. Each bottle contains 100 mL.

It is available in two different strengths:

- 125 mg/5 mL (AUST R 78981)
- 250 mg/5 mL (AUST R 78982)

Who distributes Cefalexin Sandoz

Australia

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

New Zealand

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