

Keflor CD

cefaclor monohydrate modified release tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Keflor CD.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Keflor CD against the benefits they expect it will have for you.

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

Keep this leaflet with your medicine. You may need to read it again.

What Keflor CD is used for

Keflor CD is used to treat infections in different parts of the body caused by bacteria. Keflor CD can be used to treat infections of the:

- Ears, nose, throat and tonsils (upper respiratory tract)
- chest and lungs (lower respiratory tract)
- bladder and kidneys (lower urinary tract)
- skin.

Ask your doctor if you have any questions about why Keflor CD has been prescribed for you.

Your doctor may have prescribed Keflor CD for another reason.

Keflor CD is an antibiotic that belongs to a group of medicines called cephalosporins. These medicines work by killing the bacteria that are causing your infection.

Keflor CD will not work against infections caused by viruses, such as colds or flu.

Keflor CD is not recommended for use in children under 12 years of age, as there is not enough information available on its safety and effectiveness in this age group.

Keflor CD is available only with a doctor's prescription.

There is no evidence that Keflor CD is addictive.

Before you take Keflor CD

When you must not take it

Do not take Keflor CD if you are allergic to medicines containing:

- **cefaclor monohydrate**
- **any other cephalosporin**
- **any of the ingredients listed at the end of this leaflet.**

Do not take Keflor CD if you have had a severe allergic reaction to penicillin.

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

Do not give Keflor CD to a child under the age of 12 years.

Safety and effectiveness in children younger than 12 years old have not been established.

Do not take Keflor CD after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not take Keflor CD to treat any other complaints unless your doctor has instructed you to do so.

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

Before you start to take it

Tell your doctor if you have had any type of allergic reaction to penicillin antibiotics.

You may have an increased chance of being allergic to Keflor CD if you are allergic to penicillins.

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

The safety of Keflor CD in pregnancy has not been established. Your doctor will discuss the risks and benefits of taking Keflor CD during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Keflor CD passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Keflor CD while breastfeeding.

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

- kidney problems
- liver problems
- severe bowel problems
- bleeding problems.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Keflor CD.

Taking other medicines

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

Some medicines may be affected by Keflor CD or may affect how well Keflor CD works. These include:

- anticoagulants, medicines used to prevent blood clots
- salicylates or non-steroidal anti-inflammatory drugs (NSAIDs), medicines used to treat pain or inflammation
- probenecid, a medicine used to treat gout
- antacids, medicines used to treat heartburn and indigestion.

To make sure there is no problem with absorption, do not take antacids within one hour of taking Keflor CD.

Antacids may interfere with the absorption of Keflor CD.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Keflor CD

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

They may differ from the information 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 Keflor CD you need to take.

This will depend on the type of infection you have.

The usual adult dose is one tablet (375 mg) twice a day.

How to take it

Swallow the tablets whole with a glass of water.

Do not cut, crush or chew the tablets.

When to take it

Take your tablets at about the same time each day with food.

This will allow Keflor CD to have its best effect and also help you remember when to take it.

How long to take it for

Keep taking Keflor CD until you finish the pack, or for as long as your doctor recommends.

Keep taking Keflor CD for the full time 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, your infection may not clear completely or your symptoms may return.

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 the missed dose as soon as you remember, and then go back to taking Keflor CD 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) for advice, or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much Keflor CD. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling sick, vomiting, upset stomach or diarrhoea.

While you are taking Keflor CD

Things you must do

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

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Keflor CD, especially if you are being started on any new medicine.

Tell your doctor, surgeon or dentist that you are taking Keflor CD if you are about to undergo surgery or an operation.

It may affect other medicines used during surgery.

Tell your doctor if you become pregnant while you are taking Keflor CD.

If you develop itching with swelling or skin rash or difficulty breathing while you are taking Keflor CD, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

If you get severe diarrhoea, tell your doctor or pharmacist immediately. Do this even if it occurs several weeks after stopping Keflor CD.

Diarrhoea may mean that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any medicines for diarrhoea without first checking with your doctor.

If you get a sore, white mouth or tongue while taking or soon after stopping Keflor CD, 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 Keflor CD allows fungi to grow and the above symptoms to occur. Keflor CD does not work against fungal infections.

If you have to have any blood or urine tests, tell your doctor that you are taking Keflor CD.

Keflor CD may affect the results of some tests. For example, you may get a false test result with certain urine sugar tests while you are taking Keflor CD.

If you are diabetic, check with your doctor or pharmacist before using urine sugar tests.

Keflor CD may cause false test results with some urine sugar 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 must not do

Do not stop taking Keflor CD or lower the dose because you are feeling better, unless advised by your doctor.

If you do not complete the full course prescribed by your doctor, your infection may not clear completely or your symptoms may return.

Do not take Keflor CD to treat any other complaints unless your doctor tells you to.

Do not give Keflor CD to anyone else, even if they have the same condition as you

Things to be careful of

Be careful driving or operating machinery until you know how Keflor CD affects you.

Keflor CD generally does not cause any problems with your ability to drive a car or operate machinery. However, as with

many other medicines, Keflor CD may cause dizziness or drowsiness in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Keflor CD.

Keflor CD treats infections in most people, but it may have unwanted side effects in some people.

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.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

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

- diarrhoea
- itchy rash
- oral thrush (white, furry sore tongue and mouth)

- vaginal thrush (sore and itchy vagina, vaginal discharge).

The above list includes the more common side effects of Keflor CD. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- nausea (feeling sick)
- vomiting
- drowsiness
- headache
- hyperactivity, nervousness, insomnia, confusion, dizziness, hallucinations (seeing, feeling, or hearing things that are not there)
- severe muscle stiffness
- swelling of the joints with or without fever
- pain in the joints with or without fever
- itching or swelling of the skin
- yellowing of the skin or eyes
- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal

- difficulty in swallowing or breathing
- stomach (abdominal) pain or discomfort
- nosebleed
- unusual tiredness or weakness
- watery and severe diarrhoea, which may also be bloody
- fever, cough, sore throat, feeling generally unwell, skin rash (in some instances it can develop over 2 to 7 days), rashes can be painful and itchy, blistering or peeling of the skin, facial swelling, sore/red eyes or lips (in some instances reactions can be delayed by up to 3 or 4 weeks).

The above list includes serious side effects which may require medical attention. Serious side effects are rare.

Tell your doctor immediately if you notice any of the following, even if they occur several weeks after stopping treatment with Keflor CD:

- watery and severe diarrhoea, which may also be bloody
- severe stomach cramps
- fever, in combination with one or both of the above.
- fever, cough, sore throat, feeling generally unwell, skin rash (in some instances it can develop over 2 to 7 days), rashes can be painful and itchy, blistering or peeling of the skin, facial swelling, sore/red eyes or lips (in some instances reactions can be delayed by up to 3 or 4 weeks).

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

- sudden signs of allergy such as rash, itching, hives on the skin, with swelling of the face, lips, tongue or other parts of the body, which may cause difficulty in swallowing or breathing, wheezing or shortness of breath.

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

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

Other side effects not listed above may also occur in some people. Some of these side effects can only be found when your doctor does tests from time to time to check your progress. These include:

- swelling of the liver
- inflammation of the kidney.

After using Keflor CD

Storage

Keep your medicine 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.

Keep Keflor CD tablets in their pack until it is time to take them.

If you take your tablets out of the pack, they may not keep as well.

Keep Keflor CD in a cool, dry place where the temperature stays below 25°C.

Do not keep Keflor CD or any other medicine in the bathroom or near a sink.

Do not leave Keflor CD in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Keflor CD, or your medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Keflor CD is a blue, oval-shaped tablet.

Each pack of Keflor CD contains 10 tablets.

Ingredients

The active ingredient in Keflor CD is cefaclor (as cefaclor monohydrate). Each tablet contains 375 mg of cefaclor.

The tablets also contain the following inactive ingredients:

- mannitol
- hypromellose
- hyprolose
- methacrylic acid copolymer
- stearic acid
- magnesium stearate
- propylene glycol
- purified talc
- Colour Mixture Dark Blue YS-1-4273.

The tablets are gluten free.

Supplier

Keflor CD is supplied by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration number:

AUST R 58655

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