

APO-Cefaclor CD Tablets

Cefaclor monohydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about cefaclor. 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 this medicine 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 the medicine.

You may want to read it again.

What this medicine is used for

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

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

Cefaclor belongs to a group of medicines called cephalosporin antibiotics. These are closely related to penicillin antibiotics.

It works by killing the bacteria causing your infection or by stopping its growth.

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

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

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children under 12 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- cefaclor
- other cephalosporins
- any of the ingredients listed at the end of this leaflet.

Do not take cefaclor if you have had a serious allergic reaction to penicillin.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin;

Do not take this medicine 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.

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 allergies to any other medicines, foods, preservatives or dyes.

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

- kidney disease
- liver disease
- bowel conditions or diseases such as colitis
- bleeding problems.

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

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

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

Taking other medicines

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

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

- probenecid, used to treat gout or to prolong the action of certain antibiotics
- antacids containing magnesium or aluminium – if you need to take an antacid do not take it within 1 hour of taking cefaclor
- medicines used to prevent blood clots (e.g. warfarin, heparin)
- aspirin and non-steroidal anti-inflammatory medicines (NSAIDs), used for pain and inflammation.

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

Talk to your doctor about the need for an additional method of contraception while taking cefaclor.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with cefaclor.

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

Other medicines not listed above may also interact with cefaclor.

How to take this medicine

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

They may differ to the information contained in this leaflet.

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

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

For most infections, the usual dose is one 375 mg tablet taken twice a day. This may be increased to two 375 mg tablets taken twice a day for certain types of infections.

If you have severe kidney problems your doctor may tell you to take a lower dose (using a different brand) or space the doses further apart.

How to take it

Swallow the tablets whole with a full glass of water. Do not cut, crush or chew the tablets.

When to take it

This medicine is usually taken twice a day, 12 hours apart.

Take this medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it with or without food. However, this medicine will be better absorbed into the body if you take it with food.

How long to take it for

Continue taking this medicine for as long as your doctor tells you, or until you finish the pack, even if you begin to feel better after a few days.

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take 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 your medicine as you would normally.

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

This may increase the chance of you experiencing side effects.

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 the Poisons Information Centre (telephone 13 11 26) 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 of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include nausea, vomiting, severe heartburn and diarrhoea.

While you are taking this medicine

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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

Cefaclor may cause false test results with some urine sugar tests.

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 you have stopped taking this medicine.

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 this medicine, 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 this medicine allows fungi to grow and the above symptoms to occur.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

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

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how cefaclor affects you.

Cefaclor generally does not cause any problems with your ability to drive a car or operate machinery. However, cefaclor may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous

Side effects

Tell your doctor as soon as possible if you do not feel well while you are taking cefaclor.

This medicine helps most people with bacterial infections, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- mild stomach complaints, including indigestion, nausea or vomiting, mild diarrhoea or headache
- dizziness, tiredness, looking pale
- nosebleed
- hyperactivity, nervousness, insomnia, confusion, dizziness, hallucinations

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

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

- oral thrush - white, furry, sore tongue and mouth
- itching in the genital area
- vaginal thrush - sore and itchy vagina and/or discharge
- unusual muscle stiffness
- pain in the stomach or elsewhere in your body, weakness
- confusion

The above list includes serious side effects and you may need medical attention.

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

- kidney pain, blood in the urine, passing more or less urine than is normal for you, cloudy urine
- yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice)
- hallucinations
- signs of frequent infections such as fever, chills, sore throat or mouth ulcers, or other changes in your blood which you may notice as feeling tired, weak, thirsty, or easily bruised
- watery and severe diarrhoea, which may be bloody or contain mucous
- swelling or pain in the joints, with or without fever, and sometimes with a rash
- seizures (fits)
- skin rashes (including a rash which looks like measles) or hives which may be itchy
- feeling out of sorts, with fever, headache and cough, then suddenly getting spots or blisters which quickly develop into large amounts of blistering or peeling skin
- shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body rash, itching or hives on the skin

The above list includes very serious side effects and you may need urgent medical attention or hospitalisation. Serious side effects are usually very rare.

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

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

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 finishing it

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after you have finished taking this medicine:

- 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. Cefaclor can change bacteria (which are normally present in the bowel and normally harmless), so that they multiply and cause the above symptoms. You may need urgent medical attention. However, this side effect is rare.

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

Storage and disposal

Storage

Keep the tablets in the pack until it is time to take them.

If you take your medicine out of the pack it may not keep well.

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

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

Heat and dampness can destroy some medicines.

Keep this 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.

Disposal

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

Product description

What it looks like

Capsule shaped, biconvex, unscored, blue film-coated tablet, imprinted with "Cefaclor CD 375mg" in black. AUST R 76226.

Available in blister packs of 10 tablets.

Ingredients

Each tablet contains 375 mg of cefaclor monohydrate as the active ingredient.

It also contains the following:

- hypromellose
- hypromellose
- lactose monohydrate
- silica-colloidal anhydrous
- magnesium stearate
- talc-purified
- titanium dioxide
- macrogol 400
- indigo carmine
- iron oxide black
- propylene glycol
- methanol
- isopropyl alcohol.

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113
Tel: (02) 8877 8333

Web: <http://www1.apotex.com/au>

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was prepared in December 2019.