

APO-Cefaclor CD Tablets

Contains the active ingredient cefaclor (as cefaclor monohydrate)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

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

What this medicine is used for

The name of your medicine is APO-Cefaclor CD tablets. It contains the active ingredient cefaclor (as cefaclor monohydrate).

It is used to treat infections caused by bacteria in different parts of the body such as:

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

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.

How it works

Cefaclor is an antibiotic which belongs to a group called cephalosporins. These are closely related to penicillins.

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.

There is no evidence that this medicine is addictive.

Use in children

These tablets should not be taken by children under 12 years of age.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You are hypersensitive to, or have had an allergic reaction to:
 - cefaclor
 - other cephalosporins
 - penicillin (a major allergy)
 - any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: cough, 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines including cephalosporins, penicillins, other antibiotics or things known to cause allergy. You may have an increased chance of being allergic to cefaclor if you are allergic to cephalosporins or penicillins or other allergens.
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney disease
 - liver disease
 - bowel conditions or diseases such as colitis
 - bleeding problems
3. You are currently pregnant or you plan to become pregnant.
Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed.
Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
5. You are currently receiving or are planning to receive dental treatment.

6. You are taking or are planning to take any other medicines.

This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with cefaclor. These include:

- probenecid, a medicine used to treat gout or to prolong the action of certain antibiotics
 - magnesium or aluminium containing antacids
 - medicines used to prevent blood clots such as warfarin, and heparin
 - aspirin and non-steroidal anti-inflammatory medicines, used for pain and inflammation
 - 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.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with cefaclor.

How to take this medicine

Follow carefully all directions given to you by your. Their instructions may be different to the information in this leaflet.

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 adult dose is one tablet twice a day. This may be doubled to two tablets 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.

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

How to take it

Swallow the tablets whole with a full glass of water.

The tablets should not be cut, crushed or chewed.

When to take it

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

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

It does not matter if you take it before, with or after food, but more is absorbed into the body if you take it with food.

How long to take it for

Keep 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 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 missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much cefaclor, you may develop:

- nausea
- vomiting
- severe heartburn
- diarrhoea.

While you are taking this medicine

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, 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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you become pregnant or plan to breastfeed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- 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 this medicine affects you.

Cefaclor generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, cefaclor may cause dizziness or tiredness in some people.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking cefaclor or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

- oral thrush - white, furry, sore tongue and mouth
- vaginal thrush - sore and itchy vagina and/or discharge
- itching in the genital area
- mild stomach upsets, such as indigestion, nausea or vomiting
- mild diarrhoea
- headache
- dizziness, tiredness, looking pale
- nosebleed

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

These may be serious side effects and you may need medical attention:

- skin rashes (including a rash which looks like measles) or hives which may be itchy
- 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
- unusual muscle stiffness
- swelling or pain in the joints, with or without fever, and sometimes with a rash
- vomiting
- watery and severe diarrhoea, which may be bloody or contain mucous
- pain in the stomach or elsewhere in your body
- weakness
- confusion, hallucinations
- yellowing of the skin or eyes, and/or pale stools, dark urine (jaundice).

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- kidney pain, blood in the urine, passing more or less urine than is normal for you
- seizures (fits)

- 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.

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

Allergic reactions

If you think you are having an allergic reaction to cefaclor, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Cefaclor CD tablets looks like

375 mg CD tablet: Biconvex, capsule shape and coloured blue. CEACLOR CD 375 mg is printed in black ink on the tablet.

Cartons containing blister packs of 10 tablets.

Ingredients

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

It also contains the following inactive ingredients:

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

- isopropyl alcohol.

This medicine is gluten-free, sucrose-free, tartrazine-free and free of any other azo dyes.

Australian Registration Numbers

APO-Cefaclor CD 375 mg Tablets (blister):
AUST R Number 76226

Sponsor

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