

APO-Cefaclor Oral Suspension

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)
- ears, nose, throat and tonsils (upper respiratory tract)
- bladder and kidneys (urinary tract)
- skin

How it works

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 it 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 premature infants or infants under 1 month 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 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
- medicines used to prevent blood clots (e.g. warfarin, heparin)
- aspirin and non-steroidal anti-inflammatory medicines, used for pain and inflammation
- antacids containing magnesium or aluminium, used to treat stomach upsets or stomach ulcers.

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 from your doctor or pharmacist carefully.

They may differ to the information contained in this leaflet.

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

How much to take

Your doctor or pharmacist 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 250 mg taken two or three times daily (twelve or eight hours apart). For some infections, this dose may be increased to 500 mg taken every eight hours.

The usual dose for a child will depend on his or her bodyweight and will be calculated by your doctor.

If you are elderly or have severe kidney problems, your doctor may tell you to take a lower dose or space the doses further apart.

How to take it

Cefaclor powder for suspension must be mixed with water before use. This is usually done by your pharmacist.

This medicine is taken by mouth.

Shake the bottle well and accurately measure the dose medicine measure.

Shaking the bottle and using a medicine measure will make sure that you get the correct dose. You can buy a medicine measure from your pharmacist.

If you need to take an antacid tablet for indigestion, take it at least one hour before or after taking cefaclor.

When to take it

This medicine is usually taken two or three times each day, spaced evenly apart. Take it at about the about same time each day.

Taking your medicine 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 without or without food.

How long to take it for

Continue taking this medicine for as long as your doctor tells you, or until you finish the bottle, 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 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 your medicine as you would normally.

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

This may increase the chance of unwanted 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 or 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 are taking cefaclor.

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

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

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 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 cefaclor, 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 cefaclor 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 your dosage without first checking with your doctor.

Things to be careful of

Be careful while 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 or pharmacist 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.

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, feeling sick, vomiting, mild diarrhoea or headache
- dizziness, tiredness, looking pale
- nosebleed
- hyperactivity, nervousness, problems sleeping

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

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

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

Keep your reconstituted liquid medicine in the refrigerator where the temperature stays between 2 and 8°C. Keep the lid tightly closed.

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

Do not use any of the liquid left in the bottle after fourteen days from when it was prepared.

Product description

What it looks like

APO-Cefaclor suspension comes in two strengths:

- 125mg/5mL: red, sweet, strawberry flavoured suspension in a translucent bottle with a white lid. Bottles of 100 mL when reconstituted.
AUST R 226396
- 250mg/5mL: red, sweet, strawberry flavoured suspension in a translucent bottle with a white lid. Bottles of 75 mL when reconstituted.
AUST R 226397

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

APO-Cefaclor suspension contains either 125 mg or 250 mg of cefaclor monohydrate as the active ingredient.

It also contains the following:

- xanthan gum
- sodium benzoate
- sucrose
- colloidal anhydrous silica
- allura red AC
- strawberry flavouring

- sodium citrate dihydrate
- citric acid
- simethicone emulsion.

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

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

APO and APOTEX are registered trademarks of Apotex Inc.

This leaflet was prepared in September 2018.