

APO-Cefaclor Oral Suspension

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.

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. 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)
- ears, nose, throat and tonsils (upper respiratory tract)
- bladder and kidneys (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 it 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.

This medicine is not expected to affect your ability to drive a car or operate machinery, but make sure you know how it affects you before driving.

Use in children

There is not enough information to recommend the use of this medicine in premature infants or infants under 1 month of age.

Use in the elderly

If you are elderly you may need to take lower doses of this medicine or space the doses further apart.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- it has passed the expiry date (EXP) printed on the pack.
- the packaging is torn, shows signs of tampering or it does not look quite right.
- **you have had an allergic reaction to cefaclor, other cephalosporins, penicillins or 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 hayfever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

This medicine must not be given to premature infants or infants under 1 month of age.

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, 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 have recently been vaccinated or plan to get a vaccination.
6. You are planning to have surgery.
7. You are currently receiving or are planning to receive dental treatment.

8. 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
- medicines used to prevent blood clots such as warfarin, and heparin
- aspirin and non-steroidal anti-inflammatory medicines, used for pain and inflammation
- magnesium or aluminium containing antacids, medicines used to treat stomach upsets or stomach ulcers.

If you are taking any of these you may need a different dose 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.

Other medicines not listed above may also interact with cefaclor.

How to take this medicine

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

Their instructions may be different to the information in this leaflet.

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.

The usual dose for an adult is 250mg, two or three times daily (twelve or eight hours apart). For some infections this dose may be 500mg 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 your doctor may tell you to take a lower dose 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

This medicine is taken by mouth.

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

Shake the bottle well before measuring the dose indicated on the label, with a metric measure.

If you need to take an antacid tablet for indigestion, leave a gap of 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 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 before, with or after food.

How long to take it for

Keep 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.

If you forget to take it

If it is almost time for 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 unwanted side effects.

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

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 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.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed (tell your doctor immediately)
- you are about to have any blood or urine tests. For example, if you are diabetic your urine sugar tests may be affected by cefaclor.
- you are going to have surgery.

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 are taking cefaclor.

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 complaints unless your doctor or pharmacist tells you to stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Be careful while 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 or pharmacist 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 or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild:

- 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 or feeling sick
- mild diarrhoea

- headache
- dizziness, tiredness, looking pale
- hyperactivity, nervousness, problems sleeping.

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

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- 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
- 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)
- cloudy urine.

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 are usually very rare. 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.

Allergic reactions

If you think you are having an allergic reaction to cefaclor, stop taking 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
- hayfever-like symptoms

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 its original packaging it may not keep well.

Keep your reconstituted liquid medicine in the refrigerator where the temperature will stay 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

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

Product description

What APO-Cefaclor looks like

APO-Cefaclor suspension comes in two strengths:

- 125mg/5mL: red, sweet, strawberry flavoured suspension in a translucent bottle with a white lid.
- 250mg/5mL: red, sweet, strawberry flavoured suspension in a translucent bottle with a white lid.

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

Ingredients

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

It also contains the following inactive ingredients:

- xanthan gum
- sodium benzoate
- sucrose
- colloidal anhydrous silica
- allura red AC
- strawberry flavouring
- sodium citrate
- citric acid
- simethicone.

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

Australian Registration Numbers

- **APO-Cefaclor 125mg/5mL Oral Suspension**
Bottles of 100 mL when reconstituted.
AUST R Number: 226396
- **APO-Cefaclor Oral Suspension 250mg/5mL**
Bottles of 75 mL when reconstituted.
AUST R Number: 226397

Sponsor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

Apotex Pty Ltd is the licensee of the registered trade marks APO and APOTEX from the registered proprietor, Apotex Inc.

This leaflet was last updated in August 2014.