

Ceclor[®]

cefaclor monohydrate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Ceclor. 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 taking Ceclor 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 this medicine.

You may need to read it again.

What Ceclor is used for

Ceclor contains cefaclor monohydrate as the active ingredient.

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

- ears, nose, throat and tonsils (upper respiratory tract)
- chest and lungs (lower respiratory tract)

- bladder and kidneys (urinary tract)
- skin.

This medicine belongs to a group of antibiotics called cephalosporins. These antibiotics work by killing the bacteria that are causing your infection.

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

Your doctor may have prescribed it for another reason.

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

There is no evidence that it is addictive.

Before you take it

When you must not take it

Do not take Ceclor if you have ever had an allergic reaction to:

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

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

Symptoms of an allergic reaction may include shortness

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

Do not give this medicine to a child under the age of one month.

Safety and effectiveness in children younger than one month have not been established.

Do not take this medicine after the expiry date printed on the carton and bottle label 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 this medicine to treat any other complaints unless your doctor has instructed you to do so.

Before you start to take it

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

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

- kidney disease
- severe bowel conditions
- liver disease.

Tell your doctor if you are pregnant or plan to become

pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of these things, tell them before you start taking Ceclor.

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 may interfere with Ceclor. These include probenecid (e.g. Pro-Cid).

Your doctor or pharmacist has more information on other medicines to be careful with or avoid while taking Ceclor.

How to take it

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

They may differ from the information contained in this leaflet.

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

How much to take

Your doctor will tell you how much Ceclor you need to take.

This will depend on the type of infection you have.

How to take it

Carefully follow the instructions on the carton or bottle label.

Shake the bottle well and accurately measure the dose with a 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.

It does not matter if you take this medicine with or without food.

How long to take it

Continue taking Ceclor for as long as your doctor tells you.

It is important to complete the full course prescribed by your doctor, even if you begin to feel better after a few days. If you do not, the bacteria causing your infection may continue to grow and multiply so that 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 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 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 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 Ceclor. 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 it

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 any other doctors, dentists and pharmacists who are treating you that you are taking Ceclor, especially if you are being started on any new medicines.

Tell your doctor, surgeon or dentist that you are taking Ceclor 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 this medicine.

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

It may interfere with the results of some 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.

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

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

Things you must not do

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

Do not give your medicine to anyone else even if their symptoms seem similar to yours.

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

Things to be careful of

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

It may cause dizziness or drowsiness in some people.

Children should be careful when riding bicycles or climbing trees.

Side effects

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

This medicine helps most people with infection, 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.

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 or mouth
- vaginal thrush - sore and itchy vagina and/or discharge.

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

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

- nausea
- vomiting
- drowsiness
- headache
- hyperactivity, nervousness, insomnia, confusion, dizziness, hallucinations
- 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 and eyes
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- difficulty in swallowing or breathing.

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, particularly if they occur several weeks after stopping treatment with Ceclor:

- 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.

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 your nearest hospital, if you notice any of the following:

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

This is a very serious side effect requiring urgent medical attention or hospitalisation. This side effect is very rare.

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

Other side effects not listed above may also occur in some people including:

- swelling of the liver
- inflammation of the kidney.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking it

Storage

Keep Ceclor suspension in your refrigerator at 2-8 degrees Celsius where young children cannot reach it. Do not freeze.

Keep the bottle tightly closed.

The suspension should be shaken well before use and discarded after 14 days.

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 that is left over.

Product Description

What it looks like

Your pharmacist will make up the medicine in the bottle before dispensing it to you. The resulting suspension is pink and has a strawberry taste.

It is available in two different strengths:

- 125 mg/5 mL
- 250 mg/5 mL.

Ingredients

Active ingredient:

Ceclor contains cefaclor monohydrate equivalent to either 125 mg/5 mL or 250 mg/5 mL of cefaclor.

Inactive ingredients:

- sucrose
- erythrosine
- methylcellulose
- sodium lauryl sulfate
- strawberry flavour 52312 AP0551
- xanthan gum
- starch - tapioca
- dimethicone 350.

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

Sponsor

Aspen Pharmacare Australia Pty Ltd
34-36 Chandos Street
St Leonards NSW 2065

Australian Registration Numbers:

125 mg/5 mL: AUST R 54899
250 mg/5 mL: AUST R 54898

This leaflet was prepared in December 2009.