

OZCEF

Cefaclor Modified Release Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OZCEF. It does not contain all the available information.

It does not take the place of talking to your doctor and pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking OZCEF against the benefits it is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

OZCEF tablets contain cefaclor monohydrate as the active ingredient.

What OZCEF is Used For

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

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

- chest and lungs (lower respiratory tract)
- bladder and kidneys (lower urinary tract)
- skin

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

OZCEF belongs to a group of antibiotics called cephalosporins, which are closely related to penicillins.

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

Your doctor may have prescribed OZCEF for another reason. Ask your doctor if you have any questions about why OZCEF has been prescribed for you.

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

There is no evidence that OZCEF is addictive.

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

Before you start using OZCEF tablets

When you must not take it

Do not take OZCEF tablets if:

- **You have an allergy to OZCEF, cefaclor, other cephalosporins or any of the ingredients listed at the end of this leaflet.** Some of the 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.

- **You have had a serious allergic reaction to penicillins**
- The packaging is torn or shows signs of tampering
- The expiry date on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well (or it may make you feel sick).

Do not give OZCEF to a child under the age of 12 years. The safety and efficacy of this product in children has not been established.

If you are not sure whether you should start using OZCEF, talk to your doctor.

Before you take it

You must tell your doctor:

1. If you have any type of allergic reaction to cephalosporin medicines, penicillin medicines or any other antibiotic medicines. You may have an increased chance of being allergic to OZCEF if you are allergic to cephalosporins or penicillins.
2. If you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes
3. If you have or have ever had any other health problems/medical conditions, including:
 - kidney disease
 - severe bowel conditions/disease
 - liver disease

4. If you are pregnant or intend to become pregnant
Your doctor will discuss the risks and benefits of using OZCEF during pregnancy.
5. If you are breast-feeding or plan to breast-feed.
Your doctor will discuss the risks and benefits of using OZCEF when breast-feeding.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines may interfere with OZCEF.

These include:

- antacids
If you need to take an antacid, do not take it within 1 hour of taking OZCEF.
- Probenecid (e.g. Pro-Cid)

These medicines may be affected by OZCEF, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking OZCEF.

How OZCEF is taken

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 pack, ask your doctor or pharmacist for help.

How much to take

Your doctor will decide what dose and how long you will receive OZCEF. This depends on your

infection and other factors, such as your weight.

How to take it

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

Keep taking this medicine for the full time of treatment, even if you begin to feel better after a few days.

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

When to take it

Take OZCEF at about the same time each day with food.

This will have the best effect. It will also help you to remember when to take the tablets.

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 it as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

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

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 Poisons Information Centre (telephone 13 11 26) or go to casualty at your nearest hospital if you think that you or anyone else may have taken too much OZCEF. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places/services handy.

If you take too many OZCEF tablets, you may have:

- sick
- vomiting
- upset stomach
- diarrhoea

While you are using OZCEF tablets

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 OZCEF has been stopped.

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 OZCEF, 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 OZCEF allows fungi to grow and the above symptoms to occur. OZCEF does not work against fungi.

If you become pregnant while you are taking OZCEF, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are taking OZCEF.

If you have to have any blood or urine tests, tell your doctor you are taking OZCEF tablets. OZCEF may affect the results of some blood and urine tests.

Tell all the doctors, surgeons or dentists and pharmacists who are treating you that you are receiving

OZCEF if you are about to undergo surgery or an operation.

It may affect other medicines used during surgery.

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.

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

Things you must not do

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

Do not use OZCEF to treat any other complaints unless your doctor tells you to.

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

Things to be careful of

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

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

Side Effects

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

Like other medicines, OZCEF can cause some side effects. If they occur, most are likely to be minor and temporary. However some may be serious and need medical attention.

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

While you are taking it

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

- Oral thrush – white, furry, sore tongue and mouth
- Vaginal thrush – sore and itchy vagina and/or discharge
- Itchy rash
- Diarrhoea

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 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 or 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 OZCEF:

- 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.

These are very serious side effects of OZCEF. If you have them, you may have had a serious allergic reaction to OZCEF. You may need 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.

These include:

- 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 using OZCEF tablets

Storage

At home, keep your OZCEF tablets in their original packs until it is time to use them. If you take the tablets out of the pack, they may not keep well.

Keep it in a cool, dry place where the temperature stays below 25°C. Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

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 tells you to stop taking OZCEF or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

hypromellose and isopropyl alcohol.

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

Sponsor

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Australia

Australian Registration No:
AUST R 122376

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Product description

What it looks like

OZCEF 375mg - blue tablets marked with Cefaclor CD 375 mg in black.

OZCEF tablets are available in a pack of 10 tablets.

Ingredients

Active ingredient:

OZCEF tablets contain cefaclor monohydrate equivalent to 375 mg of cefaclor

Inactive ingredients:

- hypromellose
- hydroxypropyl cellulose
- lactose
- magnesium stearate
- purified talc
- colloidal anhydrous silica.

The film coating contains: hypromellose, titanium dioxide, polyethylene glycol, indigo carmine CI73015.

The printing ink contains: purified water, iron oxide, propylene glycol,