

OZCEF®

Cefaclor Oral Suspension

Consumer Medicine Information

What is in this leaflet

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

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

All medicines have benefits and risks. 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.

What OZCEF is used for

OZCEF suspension contains the active ingredient, cefaclor (as cefaclor monohydrate).

Cefaclor is an antibiotic used to treat infections in different parts of the body caused by bacteria.

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

Cefaclor belongs to a group of antibiotics called cephalosporins (ke-fä-lö-spör-ins) which are closely related to penicillins.

Cefaclor 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.

Before you start to take OZCEF

When you must not take it

Do not take OZCEF if you have an allergy to cefaclor or other cephalosporins or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty breathing, swelling of the face, lips or tongue.

Do not take OZCEF if you have had a serious allergic reaction to penicillins.

Do not take **OZCEF** if the packaging is torn or shows signs of tampering.

Do not take **OZCEF** if the expiry date (EXP) 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).

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

Before you start taking it

Tell your doctor or pharmacist 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.

Tell your doctor or pharmacist if you have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have ever had any other health problems/medical conditions, including:

- kidney disease
- severe bowel conditions/disease
- liver disease.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant. Your doctor or pharmacist will discuss the risks and benefits of using **OZCEF** during pregnancy.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed. Your doctor or pharmacist will discuss the risks and benefits of using **OZCEF** when breast-feeding.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given **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:

- probenecid, a medicine used to treat gout or to prolong the action of certain antibiotics. This medicine may affect **OZCEF**, or 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**.

Talk to your doctor about the need for an additional method of contraception while taking **OZCEF**.

Some antibiotics may decrease the effectiveness of some birth control pills, although this has not been shown with **OZCEF**.

How OZCEF is taken

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.

The usual dose for an adult is 250mg, two to three times daily.

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

How to take it

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

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

OZCEF suspension is taken by mouth.

When to take it

OZCEF is usually taken two to three times each day and it can normally be taken with or without food.

How long to take it

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 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 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.

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 Accident and Emergency 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 much **OZCEF** you may have:

- nausea
- vomiting
- heartburn
- diarrhoea.

While you are using OZCEF

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 or pharmacist.

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 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 being given **OZCEF**. **OZCEF** may affect the results of some blood and urine tests.

Tell all the doctors, dentists and pharmacists who are treating you that you are receiving **OZCEF**.

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.

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 taking OZCEF

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
- mild stomach upsets, such as feeling sick
- diarrhoea.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- fever
- skin rashes which may be itchy
- vomiting
- severe diarrhoea
- yellowing of your skin and eyes.

These are all serious side effects of **OZCEF**. You may need urgent medical attention.

If you develop persistent diarrhoea while on this medication or within several weeks, contact your doctor.

If any of the following happen, stop using OZCEF and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- life threatening allergic reaction which may include skin rash, itching, difficulty breathing, swelling of face, lips or tongue
- skin rash with joint pain and fever
- decrease in urine volume.

These are all 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.

After finishing it

Tell your doctor immediately if you notice any of the following side effects, 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.

These are rare but serious side effects. You may have a serious condition affecting your bowel. Cefaclor can cause bacteria, which are harmless and normally present in the bowel, to multiply and cause the above symptoms. You may need urgent medical attention.

Do not take medicine for diarrhoea without first checking with your doctor or pharmacist.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

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

After using OZCEF

Storage

Keep **OZCEF** suspension in the refrigerator where the temperature stays between 2-8°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 **OZCEF** suspension where children cannot reach them. 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 medicine has passed its expiry date, ask your pharmacist what to do with any medicine that is left over.

Do not use any **OZCEF** suspension left in the bottle fourteen days after preparation.

Product description

What OZCEF looks like

OZCEF suspension comes in two strengths:

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

Ingredients

Active Ingredient:

Cefaclor (as cefaclor monohydrate)

Inactive Ingredients:

- xanthan gum
- sodium benzoate
- sucrose
- colloidal anhydrous silica
- allura red AC CII6035
- strawberry flavouring
- sodium citrate
- citric acid
- simethicone.

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

Australian Register Numbers

OZCEF 125mg/5mL suspension - AUST R 169127

OZCEF 250mg/5mL suspension - AUST R 169128

Sponsor

Ranbaxy Australia Pty Ltd

ABN 17 110 871 826

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Australia

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