ALTACEF® FILM COATED TABLET

Cefuroxime Axetil USP (250mg, 500mg)

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What ALTACEF® is used for

ALTACEF® is used in adults and children to treat infections of the:

- Ears, nose and throat
- Lungs or chest
- Urinary tract
- Skin and soft tissues

ALTACEF® is also used to treat:

- Sexually transmitted infections

Your doctor should test the type of bacteria causing your infection and monitor whether the bacteria are sensitive to ALTACEF® during your treatment

How ALTACEF® works

ALTACEF® belongs to a group of medicines called cephalosporin. It works by killing bacteria that cause infections.

Before you use ALTACEF®

When you must not use it

Do not use ALTACEF®:

- if you are allergic *(hypersensitive)* to cefuroxime or cephalosporin antibiotics or any of the other ingredients of ALTACEF®.

ALTACEF® is not recommended for children aged under 3 months, as it has not been adequately studied in this age group.

Before you start use it

Special care is indicated if you have experienced an allergic reaction to penicillin or other beta-lactam antibiotic (penicillins, monobactams and carbapenems).

There is only limited information about the safety of ALTACEF® in pregnant women. If you are pregnant your doctor will discuss with you if the benefits of taking ALTACEF® outweigh the possible risks to your baby.

The ingredients in ALTACEF® can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take ALTACEF®.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, if you have taken any recently, or if you start taking new ones. This includes medicines bought without a prescription.

Medicines used to reduce the amount of acid in your stomach (e.g. antacids used to treat heartburn) can affect how ALTACEF® works.

• Tell your doctor or pharmacist if you are taking any medicine like this.

ALTACEF® may reduce how well the contraceptive pill works. If you are taking the contraceptive pill while you are being treated with ALTACEF® you also need to use a barrier method of contraception (such as condoms). Ask your doctor for advice.

How to use ALTACEF®

How much to use

Always take ALTACEF® exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure. If you have kidney problems your doctor may reduce your frequency.

Dosage in adults:

The usual dose of ALTACEF® is 250mg to 500mg twice daily depending on the severity and type of infection.

The dose for uncomplicated sexually transmitted infections is single dose of 1g.

Dosage in children:

The usual starting dose of ALTACEF® is 125mg to 250mg twice daily depending on the severity and type of infection.

Depending on the illness or how you or your child responds to treatment, the starting dose may be changes. More than one course of treatment may be needed.

When to use it

ALTACEF® should be taken after food for optimum absorption. Swallow the tablet whole with water, with or without food.

How long to use it

The usual course of therapy is seven days (range 5 to 10 days). It is important that you take the full course of ALTACEF®. Do not stop unless your doctor advised you to – even if you feeling better. If you do not complete the full course of treatment, the infection may come back.

If you forget to use it

Do not take an extra dose to make up for a missed dose. Just take your next dose at the usual time.

If you use too much (overdose)

If you take too much ALTACEF® you

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may be more likely to have fits (seizures). Do not delay. Contact your doctor or your nearest hospital emergency department immediately. If possible, show them the ALTACEF® pack.

While you are using it

Things you must do
Take your medicine exactly as your doctor has told you.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Things you must not do
Swallow ALTACEF® whole with some water. Do not chew, crush or split the tablet – This may make the treatment less effective.

This medicine has been prescribed for you personally. Do not pass it on to other people – it may harm them even if their symptom seem to be the same as yours.

Things to be careful of
If you need a blood test:
ALTACEF® can affect the results of a test for blood sugar levels, or a blood screen called the Coombs test. If you need a blood test:

- Tell the person taking the sample that you have taken ALTACEF®
- ALTACEF® can make you dizzy and have other side effects that make you less alert
- Do not drive or use machines unless you are feeling well.

Side effects
Like all medicines, ALTACEF® can cause side effects, although not everybody gets them.
ALTACEF® may cause severe allergy and serious skin reactions.
Stop using ALTACEF® and seek medical assistance immediately if you experience any of the following symptoms:

- Skin reddening, blisters, rash, fever, sore throat or eye irritation.

Severe allergic reactions
These are very rare in people taking ALTACEF®. Signs include:

- Raised and itchy rash (hives)
- Swelling, sometimes of the face or mouth, causing difficulty in breathing
- Collapse

Serious skin reactions

- Skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) *erythema multiforme*
- A widespread rash with blisters and skin peeling on much of the body surface (*toxic epidermal necrolysis*), particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*).

Fungal infections
On common occasions, medicines like ALTACEF® can cause an overgrowth of yeast (*Candida)* in the body which can lead to fungal infections (such as thrush). This side effect is more likely if you take ALTACEF® for a long time.

On rare occasion, medicines like ALTACEF® can cause inflammation of the large intestine, causing diarrhoea, usually with blood and mucus, stomach pain, fever.

Common side effects
These may affect up to 1 in 10 people:

- Headache
- Dizziness
- Nausea (Feeling sick)
- Stomach pain

Uncommon side effects that may show up in blood tests:

- Decrease in number of blood platelets
- Decrease in the number of white blood cells

If you get side effects

- Tell your doctor or pharmacist if any of the side effects listed becomes severe or troublesome, or if you notice any side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of ALTACEF®
Storage
Keep out of the sight and reach of children.
Do not store above 30 °C.
Store in the original package in order to protect from moisture.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Disposal
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like
White coloured, capsule shaped, film-coated tablet

250mg:
debossed '250' on one side and plain on the other side.

500mg:

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debossed '500' on one side and
plain on the other side.

Ingredients

Active ingredient:
Cefuroxime axetil USP
(amorphous) equivalent to
Cefuroxime.

Inactive ingredients:
Microcrystalline Cellulose,
Colloidal Silicon Dioxide
Hydrogenated Castor Oil
Croscarmellose sodium,
Sodium lauryl sulphate
Hypromellose, 3cps
Hypromellose, 15cps
Purified Talc
Titanium Dioxide
Propylene glycol
Isopropyl Alcohol
Dichloromethane

MAL number

Manufacturer:
Zeiss Pharma Limited
Unit II IGC, SIDCO, Phase II
Samba, J & K -184121 India.

Product Registration Holder
Glenmark Pharmaceuticals
(Malaysia) Sdn Bhd (660397-W)
D-31-02, Menara Suezcap 1,
No. 2, Jalan Kerinchi,
59200 Kuala Lumpur, Malaysia

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