

AXCEL CEFUROXIME-500MG TABLET

Cefuroxime Axetil equivalent to Cefuroxime 500mg

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What Axcel Cefuroxime-500mg Tablet is used for

Axcel Cefuroxime-500mg Tablet is used for:

- Upper respiratory tract infections for example; ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis and pharyngitis.
- Lower respiratory tract infections for example; pneumonia (lung infection), acute bronchitis, and acute exacerbations of chronic bronchitis.
- Genito-urinary tract infections for example; pyelonephritis (inflammation of the kidney), cystitis (inflammation of the bladder) and urethritis (inflammation of the urethra).
- Skin and soft tissue infections for example; furunculosis, pyoderma and impetigo.
- Gonorrhoea (sexually transmitted infection), acute uncomplicated gonococcal urethritis, and cervicitis (inflammation of the cervix).

How Axcel Cefuroxime-500mg Tablet work

Cefuroxime inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins (PBPs). This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

Before you use Axcel Cefuroxime-500mg Tablet

– When you must not use it

Do not take Axcel Cefuroxime-500mg Tablet:

- If you are allergic to cephalosporin antibiotic

Some of the symptoms of allergic reaction may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue.

Special care should be given when taking Axcel Cefuroxime-500mg Tablet if:

- You are allergic to penicillin or other beta lactam antibiotic
- You are pregnant
- You are a nursing mother

– Before you start to use it

Tell your doctor if:

- You are allergic to any medicines.
- You have had a serious allergic reaction to penicillins. There may be an increased risk of you being allergic to Cefuroxime if you are allergic to penicillins.
- You are receiving concurrent treatment with potent diuretics.

Please consult your doctor before starting to use Axcel Cefuroxime-500mg Tablet if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking Axcel Cefuroxime-500mg Tablet against the benefits they expect it will have for you.

– Taking other medicines

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Cefuroxime-500mg Tablet:

- Frusemide (water pills)
- Probenecid for gout
- Medicines that reduce gastric acidity
- Cephalosporins

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Cefuroxime-500mg Tablet.

How to use Axcel Cefuroxime-500mg Tablet

– How much to use

For oral administration only.

Axcel Cefuroxime-500mg Tablet should be taken after food for optimum absorption.

Adults

Disease	Dose
Most infections	250mg twice daily
Urinary tract infections	250mg twice daily
Mild to moderate lower respiratory tract infections	250mg twice daily
More severe lower respiratory tract infections, or if pneumonia (lung infection) is suspected	500mg twice daily
Pyelonephritis (kidney infection)	250mg twice daily
Uncomplicated gonorrhoea (bacterial sexually transmitted infection)	Single dose of 1g

Sequential therapy:

Pneumonia (lung infection):

1.5 g cefuroxime injection (cefuroxime sodium) twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily Axcel Cefuroxime Tablet (cefuroxime axetil) oral therapy for 7 to 10 days.

Acute exacerbations of chronic bronchitis:

750 mg cefuroxime injection (cefuroxime sodium) twice daily (given i.v. or i.m.) for 48 to 72 hours, followed by 500 mg twice daily Axcel Cefuroxime Tablet (cefuroxime axetil) oral therapy for 5 to 10 days.

Children

Most infections	125 mg (1 x 125 mg tablet) twice daily
Children with otitis media (middle ear)	250 mg (1 x 250 mg tablet or 2 x 125 mg tablets)

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inflammation) or with more severe infection	twice daily
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If you have kidney problems your doctor may reduce your frequency.

There is no experience of using Axcel Cefuroxime Tablet in children under the age of 3 months.

– When to use it

Your doctor will decide when it is appropriate for you to use Axcel Cefuroxime-500mg Tablet according to the type of condition you have.

– How long to use it

The usual course therapy is a seven days (range 5 to 10 days). Continue taking Axcel Cefuroxime-500mg Tablet for as long as doctor recommends.

– If you forget to use it

- Consult your doctor or pharmacist on what you should do if you forget to use it.
- Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

– If you use too much (overdose)

It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital if you did take Axcel Cefuroxime-500mg Tablet too much.

Taking too many tablets may cause seizure.

While you are using it

– Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Axcel Cefuroxime-500mg Tablet.

- Tell your doctor immediately if you become pregnant while taking this medication.
- Tell your doctor if unexpectedly you need to take any other medicines.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.
- If you get severe diarrhoea tell your doctor or pharmacist immediately.

– Things you must not do

- Do not stop taking the medicine before you complete your antibiotic therapy course.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Cefuroxime-500mg Tablet to anyone else, even if they have the same symptoms or condition as you.
- Do not take your medicine more than the suggested frequency in a day.
- Do not overdosage the medicine during any single consumption.

– Things to be careful of

- Pregnancy and lactation.
- Be careful driving or operating machinery until you know how Axcel Cefuroxime-500mg Tablet affects you.

Side effects

Like all medicines, Axcel Cefuroxime-500mg Tablet can cause side effects although not everybody gets them. You are advised to consult doctor / pharmacist for further information. The following side effects have been reported:

- **Infections and infestations:** overgrowth of candida
- **Blood and lymphatic system disorder:** Increase in eosinophil in blood, positive Coombs test, deficiency in platelets, deficiency in white blood cells and deficiency in red blood cells.
- **Immune system disorders:** Skin rash, urticaria (a raised, itchy rash that appears on the skin), pruritus (severe itching of

the skin), drug fever (fever after administration of the medicine) serum sickness (allergic reaction) and anaphylaxis (acute allergic reaction).

- **Nervous system disorders:** Headache, dizziness.
- **Gastrointestinal disorders:** Diarrhoea, nausea, abdominal pain, vomiting, and Pseudomembranous colitis (inflammation of colon).
- **Hepatobiliary disorders:** Transient increases of hepatic enzyme levels, jaundice and hepatitis (inflammation of the liver).
- **Skin and subcutaneous tissue disorders:** Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (skin rash and reaction due to hypersensitivity).

Axcel Cefuroxime-500mg Tablet may cause severe allergy and serious skin reactions. Stop using Axcel Cefuroxime-500mg Tablet and seek medical assistance immediately if you experience any of the following symptoms:

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

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.moh.gov.my (Public→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and disposal of Axcel Cefuroxime-500mg Tablet

– Storage

Keep Axcel Cefuroxime-500mg Tablet out of reach of children. Store below 30°C. Protect from light and moisture.

– Disposal

Do not use Axcel Cefuroxime-500mg Tablet after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose

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medicines no longer required. These measures will help to protect the environment.

Product description

– What it looks like

White to off white, biconvex, capsule shape tablet with a scoreline on one side and B032 on other side.

– Ingredients

Active Ingredient:

Cefuroxime Axetil

Inactive Ingredients:

Croscarmellose Sodium, Sodium Lauryl Sulphate, Magnesium Stearate, Opadry II White YS-1-7040, Purified Water.

– MAL Number

MAL21036034AZ

Manufacturer and product registration holder

KOTRA PHARMA (M) SDN. BHD.

No. 1, 2 & 3, Jalan TTC 12,

Cheng Industrial Estate,

75250 Melaka, Malaysia.

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