

SPIZEF TABLETS

Cefuroxime Axetil (250 and 500mg)

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What SPIZEF is used for

Your doctor may have prescribed SPIZEF tablets to treat one of the following infections of:

- The throat, nose or ear.
- The lungs or chest.
- The urinary tract.
- The skin and soft tissues.
- The sexually transmitted diseases

How SPIZEF works

This product belongs to a group of antibiotics called cephalosporins.

Cefuroxime works by killing bacteria that cause infections.

Before you use SPIZEF

- When you must not use it

Do not take SPIZEF if you:

- Are allergic (hypersensitive) to the active ingredient cefuroxime axetil, any other cephalosporin antibiotics or any of the other ingredients.
- Have ever had a severe allergic (hypersensitive) reaction to any other type of β -lactam antibiotic (penicillins, monobactams and carbapenems).

- Before you start to use it

Talk to your doctor or pharmacist before taking SPIZEF:

- - If you have Lyme disease (spread by infected ticks)

Taking other medicines

- Tell your doctor if you are taking any other medicines, including any that

you buy without a prescription from a pharmacy, supermarket or health food shop. For Cefuroxime, be aware of the following:

- Taking SPIZEF can interfere with certain medical test including those used to determine levels of glucose (sugar) in your blood. If you are due to have a medical test make sure that your doctor knows that you are taking SPIZEF before test. If you monitor the levels of glucose in your blood or urine yourself (e.g. diabetic) speak to your doctor or Pharmacist to see if your medicine could affect the results of your test.
- If you are taking medicine for gout (probenecid).
- The use of cefuroxime axetil may be accompanied by a false positive antibody test (Coombs test).
- Cefuroxime may reduce the effectiveness of the contraceptive pill.

Pregnancy and lactation

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. You must not take SPIZEF if you are pregnant or think you might be.

How to use SPIZEF

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Adults:

The recommended dose of SPIZEF is 125 mg to 500 mg daily, depending on the severity and type of infection.

Children:

Most Infections: 125 mg daily, to a maximum of 250 mg daily.

Children 2 years and older: Otitis Media (middle ear infection) or where appropriate, with more severe infections: 250 mg daily, to a maximum of 500 mg daily.

Spizef Tablet should not be crushed and are therefore unsuitable for children aged under 3 months, as the safety and effectiveness are not known in this age group.

- When to use it

Use twice daily or use as directed by your doctor or pharmacist.

Take SPIZEF after food. This will help to make the treatment more effective. Intakes of the tablets at approximately at the same time every day are recommended.

- How long to use it

Continue using SPIZEF for the duration that the doctor recommends.

The usual course of therapy is 7 days (Range 5 - 10 days) Continue taking SPIZEF for as long as your doctor recommends.

It is important that you complete the course of treatment even if you begin to feel better after a few days. If you stop taking Cefuroxime too soon your infection may not be completely cured and the infection may return or your condition may get worse. The bacteria causing your infection may become resistant to Cefuroxime.

- If you forget to use it

Do not take the missed dose at all. Do not take a double dose to make up for a forgotten dose. Instead, continue your regular dosing.

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much of this medicine may cause the symptoms described in side effects section.

While you are using it

- Things you must do

Cefuroxime tablets are for oral use. You should swallow your tablet with a glass of water.

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using SPIZEF.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not share SPIZEF to anyone else.

- Things to be careful of

Driving and using machines

SPIZEF may make you feel dizzy, nauseous or tired. It is therefore possible that Spizef could affect your ability to drive a car or operate machines.

Side effects

Like all medicines, SPIZEF can cause side effects, although not everybody gets them.

Stop taking SPIZEF immediately and contact your doctor or pharmacist if you experience any of the following side effects after using this medicine.

SPIZEF may cause severe allergy and serious skin reactions. Stop using SPIZEF and seek medical assistance immediately if you experience any of the following symptoms:

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

Very common side effects:

- Fungal infections. Medicines like SPIZEF 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 SPIZEF for a long time.
- Eosinophilia (increase in eosinophils in blood)
- Headache
- Dizziness
- Transient increases of liver enzyme levels.
- Gastrointestinal disturbances including diarrhea, nausea, abdominal pain

Common side effects:

Hypersensitivity reactions such as hives and itchiness have been reported.

Blood condition: Red blood cells destroyed too quickly (hemolytic anemia), decrease in the number of white blood cells.

Liver impairment: Inflammation of the liver, yellow color of the skin or whites of the eyes (jaundice).

Small number of consumers have experienced:

Gastrointestinal: Inflammation of the large intestine causing severe diarrhea, usually with blood and mucus, stomach pain, fever (Pseudomembranous colitis).

Rare side effects

Skin disorder such as Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis.

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 Vaciines (AEFI)]

Storage and Disposal of SPIZEF

- Storage

Keep out of the reach and sight of children.

Store in a dry place at a temperature not exceeding 30 °C, protect from light.

- 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

SPIZEF TABLET 250MG: Off white capsule shaped film coated tablet with 250 debossed on one side and plain on the other side.

SPIZEF TABLET 500MG: Off white capsule shaped film coated tablet with 500 debossed on one side and plain on the other side.

- Ingredients

- Active ingredient

SPIZEF TABLET 250MG: Each 250mg film coated tablet contains cefuroxime 250mg.

SPIZEF TABLET 500MG: Each 500mg film coated tablet contains cefuroxime 500mg.

- Inactive ingredients

Opadry (Y-1-7000) White, Pregelatinised Starch (1500), Croscarmellose Sodium, Colloidal Silicon Dioxide, Sodium Lauryl Sulphate, Purified Water

- MAL number(s):

SPIZEF TABLET 250MG:
MAL07122799AZ

SPIZEF TABLET 500MG:
MAL07122800AZ

Manufacturer

Orchid Healthcare
(A Division of Orchid Chemicals and
Pharmaceuticals Limited)
B77, SIDCO Industrial Estate, Alathur,
Kancheepuram District – 603110, Tamil
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Product Registration Holder

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