

Cefuroxim STADA Film coated caplet

Cefuroxime axetil (250mg, 500mg)

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What Cefuroxim STADA is used for

Your doctor has chosen this medicine to suit you and your condition. Your doctor has prescribed this medicine because you have an infection on:

- Lower respiratory tract infections: pneumonia, acute bronchitis, and acute exacerbations of chronic bronchitis.
- Upper respiratory tract infections: ear, nose and throat infections, such as otitis media, sinusitis, tonsillitis, pharyngitis.
- Genito-urinary tract infections: pyelonephritis, cystitis and urethritis.
- Skin and soft tissue infections: furunculosis, pyoderma, impetigo.
- Gonorrhoea, acute uncomplicated gonococcal urethritis, and cervicitis.

How Cefuroxim STADA works

Cefuroxime axetil which is found in Cefuroxim STADA belongs to a group of medicines called cephalosporins which is a type of antibiotic. Antibiotics kill bacteria or “germs” which cause infections.

Before you use Cefuroxim STADA

- When you must not use it

Do not take Cefuroxim STADA if you have ever had a severe allergic reaction to an antibiotic known as cephalosporins or any of the ingredients in Cefuroxim STADA. Ask your doctor

or pharmacist if you are not sure.

- Before you start to use it

Tell your doctor about all your medical conditions, including if you:

- have experienced an allergic reaction to penicillins or other beta-lactams;
- have kidney failure;
- have severe gastrointestinal disease;
- are in pregnancy
- or you are breast feeding a baby because cefuroxime is found in human milk.

- Taking other medicines

Please tell your doctor or pharmacist if you taking or have recently taken any other medicines. Because cefuroxime axetil can affect the way some other medicines works. Also some other medicines can affect the way cefuroxime axetil works.

- Avoid combination cefuroxime with medicines enhancing the pH of the stomach.
- Do not take cefuroxime 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 interfere with the determination of sugar in urine and blood.
- Cefuroxime may reduce the effectiveness of the contraceptive pill.
- Avoid antibiotics such as tetracyclines, macrolides, or chloramphenicol in conjunction with cefuroxime axetil.
- Cephalosporin antibiotics at high dosage should be given with caution to people receiving medication that elevates the rate of urination (diuretics), aminoglycoside antibiotics or antifungal medicine (amphotericin) as these combination increase the risk of toxicity to kidney cells (nephrotoxicity).

How to use Cefuroxim STADA

- How much to use

- Take your medicine as your doctor has told you. The label on it will usually tell you how many to take and

how often. If you are not sure, ask your doctor or pharmacist. The usual dose is:

- Adults: 250 mg twice daily. For more severe infections, the usual dose is 500 mg twice daily.
- Children: the usual dose is 125 mg twice daily.

The dose may vary depending on the severity of the infection. Sometimes your doctor may need to increase this dose. In infants and children, the doctor may adjust the dose according to weight and age. In this case, your doctor or pharmacist will tell you the correct dose to be taken. Cefuroxime is not recommended for children aged under 3 months.

- When to use it

With or without meals.

- How long to use it

Do not skip any doses, or stop taking Cefuroxim STADA even if you begin to feel better, until you finish your prescribed treatment according to instruction of your doctor or pharmacist. The medicine may not have killed all the germs and you may start to feel unwell again.

- If you forget to use it

If you forget your dose do not worry. Take your caplets as soon as remember, and continue to take your medicine in the usual way.

- If you use too much (overdose)

If you accidentally take too many caplets, you may feel unwell. Let your doctor know as soon as possible. If you have taken more caplets than you should, and are feeling unwell or worried, contact your doctor immediately or go to your nearest hospital casualty department. Take this leaflet or your medicine so that the staff will know what you have taken. Overdosage of cephalosporins can cause convulsions.

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While you are using it

- Things you must do

Take Cefuroxim STADA exactly as prescribed by your doctor or pharmacist until you have completed your prescribed course. Swallow the caplet whole with drink of water. Tell your doctor or pharmacist if you cannot swallow the caplet whole. Tell your doctor or pharmacist if you think your condition is not getting better while you are taking Cefuroxim STADA. Tell your doctor or pharmacist if side effects happen while you are taking Cefuroxim STADA.

- Things you must not do

Do not split, chew or crush the caplet.

- Things to be careful of

Check with your doctor or pharmacist if you:

- develop serious diarrhea during or after the treatment with Cefuroxim STADA.
- are using antibiotics for a prolonged period, as it may result in overgrowth of non-sensitive organisms.

Side effects

The side effects below may happen with this medicine:

General: hypersensitivity reactions such as skin redness and itchiness have been reported.

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

Blood condition

(Hematologic): red blood cells destroyed too quickly (hemolytic anemia), decrease in the number of white blood cells (leukopenia).

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

Body nervous system (Neurologic): (Seizure).

Skin: Hypersensitivity reaction (Erythema multiforme), severe reaction involving the skin and mucous membrane (Stevens-Johnson syndrome).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→ Reporting).

Storage and Disposal of Cefuroxim STADA

- Storage

Protect from light. Store below 30°C. Keep all medicines out of the reach and sight of children.

- Disposal

Do not use this medicinal product after the expiry date which is stated on the blister foil and the box. Medicines should not be disposed of via waste water 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

Cefuroxim STADA appears as white to off-white film coated caplet scored on one side. On the other side, Cefuroxim STADA 250mg Film coated caplet engraved "250" where Cefuroxim STADA 500mg Film coated caplet engraved "500". They are packed in aluminium/aluminium blister and packed in card box (packs of 10 film coated caplets).

- Ingredients

- Active ingredient:
Each Cefuroxim STADA 250mg Film coated caplet contains cefuroxime axetil equivalent to cefuroxime 250mg.
Each Cefuroxim STADA 500mg Film coated caplet contains cefuroxime axetil equivalent to cefuroxime 500mg.
- Inactive ingredients:
Maize starch, Microcrystalline cellulose, crocarmellose sodium, magnesium stearate, talc, hypromellose, polyethylene glycol, titanium dioxide.

- MAL numbers:

Cefuroxim STADA 250mg Film coated caplet: MAL12095075A

Cefuroxim STADA 500mg Film coated caplet: MAL12095078A

Manufacturer

Pymepharco
Pymepharco is a subsidiary of STADA Arzneimittel AG
166-170 Nguyen Hue Str, Tuy Hoa City, Phu Yen Province, Vietnam.

Product Registration Holder

Stadpharm Sdn Bhd
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