

AUROXETIL

Cefuroxime axetil (125mg, 250mg, 500mg)

Consumer Medication Information Leaflet (RiMUP)

What is in this leaflet

1. What Auroxetil is used for
2. How Auroxetil works
3. Before you take Auroxetil
4. How to take Auroxetil
5. While you are using Auroxetil
6. Side effects
7. Storage and Disposal of Auroxetil
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Auroxetil is used for

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

- Upper respiratory tract infections (including infections occurring in the ears, sinuses, tonsils and throat).
- Lower respiratory tract infections, inflammation to the lungs (Pneumonia), inflammation of the lung air passages (acute bronchitis) and acute exacerbations of chronic bronchitis.
- Bladder infections.
- Skin infections recurring boils, ulcers, contagious infection of the skin (Impetigo).
- Sexually transmitted infections such as Gonorrhoea, Gonococcal urethritis and inflammation of the cervix (cervicitis).

How Auroxetil works

Auroxetil is an antibiotic and belongs to a class of medicines called “cephalosporins”. It is active against a wide range of bacteria. It is used to treat certain types of infections and works by killing certain types of bacteria.

Before you take Auroxetil

- When you must not take it

If you are hypersensitive (allergic) to Cephalosporin class of antibiotics or any of the other ingredients of Auroxetil.

Tell your doctor if you are not sure about any of the above: your doctor will be able to advise you.

- Before you start to take it

Tell your doctor before you start to take this medicine if:

- You have previously suffered from an allergic reaction to penicillins or other beta-lactam antibiotics.
- You suffer from any other condition which causes vomiting, diarrhea as this could stop your medicine from being absorbed properly. In this case your doctor may recommend an injection of Cefuroxime.

If after starting treatment, you begin to experience symptoms of an allergic reaction stop taking your medicine and contact your doctor immediately.

If during treatment, you develop sickness and diarrhea then contact your doctor as this could stop your medicine from being absorbed properly. Indicate that you are suffering from a serious condition called “pseudomembranous colitis”.

Your medicine may cause overgrowth of other microorganisms which occur naturally in your body. This can lead to other conditions such as vaginal thrush and stomach upsets.

Pregnancy and breast-feeding

This medicine may not be suitable for you if you are pregnant or breast feeding. Talk to your doctor about using Auroxetil if you are pregnant or planning of becoming pregnant. Auroxetil is excreted in breast milk, consult your doctor before you use Auroxetil whilst breast-feeding.

- Taking other medicines

Talk to your doctor if you are taking medicines which decrease stomach acidity (such as medicines used to treat indigestion, heartburn or stomach ulcers). These could stop your medicine from being absorbed properly.

Taking Auroxetil 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 Auroxetil before test. If you monitor the levels of glucose in your blood or urine yourself (e.g. diabetic patients) speak to your doctor or

Pharmacist to see if your medicine could affect the results of your test.

How to take Auroxetil

- How much to take

• Take your medicine as your doctor has told you. The label on it will usually tell you how many to take and how often. Auroxetil works best if taken immediately after food. If you are not sure, ask your doctor or pharmacist. The usual dose is:

- Adults: Most Infections: 250 mg twice daily.
- Children: Most Infections: 125 mg twice daily, to a maximum of 250 mg daily.
- Children \geq 2 years: Otitis Media or Where Appropriate, with More Severe Infections: 250 mg twice daily, to a maximum of 500 mg daily.

- When to take it

You may take your tablets together with food or immediately after a meal. You should swallow the tablets with a glass of water.

- How long to take it

Keep taking Auroxetil until the treatment is finished, even if you feel better do not stop taking the tablets, stopping the tablets may lead to return of infection.

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

- If you forget to take it

Take Auroxetil as prescribed. However if you miss a dose, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and return to your normal dosing schedule.

Do not take a double dose to make up for a forgotten tablet.

AUROXETIL

Cefuroxime axetil (125mg, 250mg, 500mg)

Consumer Medication Information Leaflet (RiMUP)

If you often forget to take your medicine, let your doctor and pharmacist know.

- If you use too much (overdose)

If you accidentally take too many tablets, or if someone else or a child takes your medicine, talk to a doctor or pharmacist immediately.

Over dosage of cephalosporins can cause convulsions.

While you are using Auroxetil

- Things you must do

If you feel unwell or if you have concerns about a side effect, you will need to seek advice. If you feel very ill, get medical help straight away. If you have any unused medicine, return it to your pharmacist who will dispose it of safely. These measures will help to protect the environment.

- Things you must not do

You must not take the medicine after the expiry date shown on the packaging.

- Things to be careful of

Treatment with antibiotic Cefuroxime Axetil is unlikely to interfere with the ability to drive and use machines.

Side effects

Adverse reactions to Cefuroxime axetil have been generally mild and transient in nature. As with other cephalosporins, there have been rare reports of serious skin reactions:

- Erythema multiforme
- Stevens-Johnson syndrome
- Toxic epidermal necrolysis (exanthematic necrolysis)
- Hypersensitivity reactions including skin rashes, hives, itchiness, drug fever, serum sickness, and very rarely, anaphylaxis

There have been rare reports of

- Thrombocytopenia (low platelet count)
- Leucopenia (decrease in the number of white blood cell, sometimes profound)
- Jaundice

Small number of consumers have experienced

- Gastrointestinal disturbances, including diarrhea, nausea and vomiting
- Pseudomembranous colitis
- Headache
- Eosinophilia (increase in eosinophils in blood)
- Transient increases of liver enzyme levels

Cephalosporins as a class may interact with blood and produce a positive Coombs' test (which can interfere with cross-matching of blood) and very rarely, haemolytic anaemia (abnormal breakdown of red blood cell).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Auroxetil

- Storage

Keep out of the reach and sight of children.

Do not store above 30°C.

Do not use Auroxetil after the expiry date which is stated on the carton/blister after EXP.

The expiry date refers to the last day of that month.

- Disposal

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

Cefuroxime Axetil Tablets 125 mg:

White to off-white, uncoated, capsule

shaped tablets with 'A32' debossed on one side and plain on the other side.

Cefuroxime Axetil Tablets 250 mg:

White to off-white, uncoated, capsule shaped tablets with 'A33' debossed on one side and plain on the other side.

Cefuroxime Axetil Tablets 500 mg:

White to off-white, uncoated, capsule shaped tablets with 'A34' debossed on one side and plain on the other side.

- Ingredients

- Active ingredient(s)

Cefuroxime Axetil.

- Inactive ingredients

Microcrystalline cellulose (E 460), croscarmellose sodium, sodium lauryl sulphate, hydrogenated vegetable oil and colloidal silicon dioxide.

- MAL number:

Auroxetil 125 mg: MAL11125015AZ

Auroxetil 250 mg: MAL11125016AZ

Auroxetil 500mg: MAL11125017AZ

Manufacturer

Aurobindo Pharma Limited,
Unit-VI, Survey No. 329/39 & 329/47, Chitkul (V), Patancheru Mandal, Medak, District, Telangana State, India.

Regd. Office:

Plot No.: 2, Maitrivihar
Ameerpet, Hyderabad – 500 038,
Telangana State, India.

Product Registration Holder in Malaysia:

Healol Pharmaceuticals Sdn Bhd,
74-3, Jalan Wangsa Delima 6, KLSC
Wangsa Maju, 53300 Kuala Lumpur.

Date of revision

11/10/2017.

Serial Number

BPFK(R4/1)140717/00172