

AUXIMO POWDER FOR ORAL SUSPENSION

Amoxicillin / Potassium clavulanate (400mg/57mg, 200mg/28.5mg)

What is in this leaflet

1. What Auximo is used for
2. How Auximo works
3. Before you use Auximo
4. How to use Auximo
5. While you are using Auximo
6. Side effects
7. Storage and disposal of Auximo
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of RiMUP revision
11. Serial number

What Auximo is used for

Auximo is an antibiotic used in children to treat infections in different parts of the body caused by bacteria in respiratory tract, urinary tract, skin and soft tissue and dental infections.

How Auximo works

Auximo contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin is a penicillin antibiotic. Amoxicillin can sometimes be stopped from working (made inactive). The other active medicine, clavulanic acid, stops this from happening.

Before you use Auximo

- When you must not use it

Do not use this medicine if:

- Your child is allergic (hypersensitive) to amoxicillin, clavulanic acid, other penicillin based antibiotics, or similar antibiotics called cephalosporins.
- Your child has ever had liver problems or jaundice (yellowing of the skin and/or whites of the eyes) when taking an antibiotic.
- If you think any of these apply to your child, check with your doctor before you take Auximo.

- Before you start to use it

Take special care and get advice from your doctor if:

- Your child has ever had an allergic reaction to any other antibiotics or medicines. This might include a skin rash or swelling of the face or neck.
- Your child has glandular fever (mononucleosis).

- Your child is taking medicines, such as warfarin, that are used to prevent blood clots.
- Your child has liver problems.
- Your child has kidney disease.
- Your child is not urinating regularly or not able to drink very much.
- Your child has a genetic condition called phenylketonuria.

Check with your doctor if you think any of these may apply to your child. Your doctor will decide whether Auximo is suitable for your child and may need to adjust the dose or give your child a different medicine.

- Taking other medicines

Tell your doctor or pharmacist if your child is taking any other medicines, if your child has taken any recently, or if your child starts taking new ones. This includes medicines bought without a prescription.

Some medicines may affect how Auximo works, or make it more likely that your child will have side effects. Auximo can also affect how some other medicines work. These include:

- Probenecid and allopurinol (used to treat gout)
- Anticoagulants (used to prevent blood clots) such as warfarin and acenocoumarol
- Mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs)
- Methotrexate (a medicine used to treat cancer or rheumatic diseases).

Tell your doctor or pharmacist if your child is taking any of these.

How to use Auximo

- Empty the contents of a sachet into a glass and add 5mL of water.
- Stir well until the powder is completely dispersed.
- Full dose should be administered immediately after reconstitution.
- Rinse the glass with a small amount of water and administer the rinse immediately.

- How much to use

Always take Auximo exactly as your doctor or pharmacist has told you to.

Check with your doctor or pharmacist if you are not sure.

Your doctor will decide on the correct dosage for your child.

Patients with kidney or liver problems

- If your child has kidney problems, your doctor may give you a different strength or a different medicine.
- If your child has liver problems, you may have more frequent blood tests to check how your child's liver is working.

- When to use it

Take Auximo at the start of a meal or slightly before.

- How long to use it

It is important that your child takes the full course of Auximo. Don't stop unless your doctor advises you to- even if your child is feeling better. If your child doesn't complete the full course of treatment, the infection may come back. Do not take Auximo for more than 14 days. If your child still feels unwell you should go back to see your doctor.

- If you forget to use it

Don't take a double dose to make up for a missed dose. Just take it as soon as you remember.

If you are not sure what to do, ask your doctor or pharmacist.

- If you use too much (overdose)

If your child accidentally takes too much Auximo, it is unlikely to cause any serious problems. The most common side effects of taking too much Auximo are nausea, vomiting and diarrhoea.

If you are worried, or your child feels unwell, ask your doctor or pharmacist for advice.

While you are using it

- Things you must do

Check with your doctor or pharmacist before taking your medicine and take it as prescribed by your doctor.

- Things you must not do

This medicine has been prescribed for your child, and you should not pass it on

AUXIMO POWDER FOR ORAL SUSPENSION

Amoxicillin / Potassium clavulanate (400mg/57mg, 200mg/28.5mg)

to others. It may harm them, even if their symptoms are the same as your child's.

- Things to be careful of

Take special care and get advice from your doctor if:

- Your child develops a skin rash while taking Auximo
- Do not give any more suspension and tell the doctor at once

Auximo suspension contains aspartame, which is a source of phenylalanine. If your child has an intolerance to aspartame or has a condition called phenylketonuria (PKU), check with your doctor that Auximo is right for your child. Auximo suspension contains mannitol which may cause diarrhoea in your child.

Side effects

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

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

Look out for important symptoms.

Severe allergic reactions

These are very rare in people taking Auximo. Signs include:

- raised, itchy rash (hives)
- inflammation of blood vessels (vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- fever, joint pain, swollen glands in the neck, armpit or groin
- swelling, sometimes of the face or mouth (angioedema), which may cause difficulty in swallowing or breathing
- collapse
- chest pain which can be a sign of a potentially serious allergic reaction called *Kounis syndrome*.

Get medical help immediately if you get any of these symptoms. Stop taking Auximo.

Serious skin reactions

These are rare in people taking Auximo. Signs include: 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*).

These are very rare in people taking Auximo. Signs include:

- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (*Stevens-Johnson Syndrome*), and a more severe form, causing blisters and peeling skin on much of the body surface (*toxic epidermal necrolysis*)
- a widespread, red, skin rash with small blisters containing pus (*exanthematous pustulosis*)
- a red, itchy, scaly rash with blisters and bumps under the skin (*bullous exfoliative dermatitis*)
- Serious allergic reactions such as drug reaction with eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

Get medical help immediately if you get any of these symptoms. Stop taking Auximo.

Serious liver problems

On rare occasions, medicines like Auximo can cause liver problems, causing yellowing of the skin and/or whites of the eyes.

Tell your doctor as soon as possible if you get any of these symptoms.

Severe diarrhoea

(*Pseudomembranous colitis*)

On rare occasions, medicines like Auximo can cause inflammation of the colon (large intestine), causing diarrhoea, usually with blood and mucus, stomach pain and fever.

Tell your doctor as soon as possible if you get any of these symptoms.

Very common side effects

These may affect more than 1 in 10 people:

- diarrhoea (in adults)

Common side effects

These may affect up to 1 in 10 people:

- thrush (fungal infection caused by *Candida* in the vagina, mouth or skin folds)
- feeling sick (*nausea*)
- vomiting
- diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people:

- dizziness
 - headache
 - indigestion
 - skin rash
 - itching
 - itchy, bumpy rash (*hives*)
- Uncommon side effects that may show up in blood tests are:
- increase in some substances (enzymes) produced by the liver

Rare side effects

These may affect up to 1 in 1,000 people:

- 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*)
- Rare side effects that may show up in blood tests are:
- decrease in the number of white blood cells (*leucopenia*, including *neutropenia*)
 - decrease in the number of cells that help blood to clot (*thrombocytopenia*)

Very rare side effects

These may affect up to 1 in 10,000 people:

- severe allergic reactions
- serious skin reactions
- inflammation of the liver (*hepatitis*)
- yellowing of the whites of the eyes or skin (*jaundice*)
- inflammation of the large intestines
- inflammation of the kidney (*nephritis*)
- an increase in the time blood takes to clot
- being unusually active (*hyperactivity*)
- fits (*seizures*)
- black tongue which looks hairy

AUXIMO POWDER FOR ORAL SUSPENSION

Amoxicillin / Potassium clavulanate (400mg/57mg, 200mg/28.5mg)

- inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- stained teeth that can usually be removed by brushing

Very rare side effects that may show up in blood or urines tests are:

- severe decrease in the number of white blood cells (*agranulocytosis*)
- red blood cells destroyed too quickly (*haemolytic anaemia*)
- crystals in urine

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of Auximo

- Storage

- Keep all medicines out of reach of children.
- Do not take Auximo after the expiry date shown on the pack.
- After opening the aluminium pouch, the product should be used within 15 days.
- Do not store above 30°C & protect from light and moisture before and after opening the aluminium pouch.

- Disposal

Medicine 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

Dry, off-white powder with characteristic flavor which on reconstitution becomes an off-white suspension with a characteristic strawberry odour.

- Ingredients

Active ingredient(s):

Amoxicillin trihydrate

Potassium clavulanate

Inactive ingredients:

Citric acid, sodium citrate, strawberry flavor, silica colloidal anhydrous, aspartame, mannitol, hypromellose.

- MAL number:

Auximo 400mg/57mg Powder For Oral Suspension

MAL _____

Auximo 200mg/28.5mg Powder For Oral Suspension

MAL _____

Manufacturer

Imexpharm Corporation

Lot B15/I – B16/I, Vinh Loc Street 2a
Industrial Zone, Binh Hung Hoa B Ward,
Ho Chi Minh City, Vietnam.

Product Registration Holder

Stadpharm Sdn. Bhd.

E-9-01, Oasis Square, Ara Damansara,
No. 2, Jalan PJU 1A/7A, 47301 Petaling
Jaya, Selangor Darul Ehsan, Malaysia.

Date of revision

03/06/2026

Serial Number

NPRA (R2) 25/107