

Z MOX CAPSULES/ ORAL SUSPENSION

Amoxicillin (250mg, 500mg, 125mg/5ml 250mg/5ml)

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What Zmox is used for

Zmox is used to treat a wide range of infections in the body caused by bacteria. These infections may affect the

- chest (bronchitis or pneumonia)
- bladder (cystitis)
- sinuses (sinusitis)
- the ears (otitis media)
- skin, soft tissues and joints
- dental infections
- urogenital and gynaecologic infections

How Zmox works

Zmox is an antibiotic and works by killing bacteria that cause infections. Zmox belongs to a group of medicines called "penicillins".

Before you use Zmox

- When you must not use it

Do not take Zmox if you:

- are allergic (hypersensitive) to amoxicillin, penicillin or any other ingredients of amoxicillin
- have ever had allergic (hypersensitive) reaction to any antibiotic. This can include skin rash or swelling of the face or neck.
- have severe gastro-intestinal infections with persistent diarrhea or vomiting due to risk of reduced absorption.
- are individuals with allergic rashes or bronchial asthma and hay fever.

- Before you start use it

Tell your doctor if you have any of the following:

- kidney disease: your doctor may have to adjust the dose
- Leukemia: you may have a higher risk of skin reactions

- Fits (epilepsy): you may have a higher risk of seizures (fits)

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if

- You are pregnant, might become pregnant or think you may be pregnant
- You are breast-feeding or planning to breast feed.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast feeding.

Driving and using machines

This medicine has no known influence on the ability to drive and use machines

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including those obtained without prescription.

In particular tell your doctor if you are taking:

- *Allopurinol* (used to treat gout): you may have a higher risk of skin reactions
- *Contraceptive pills*: there is a risk of contraceptive pills not working to their greatest effect.
- *Probenecid*: if you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoxicillin.
- tetracyclines and chloramphenicol (bacteriostatic agent)

How to use Zmox

- How much to use

Adults and children 20 kg body weight above:

250mg-500 mg every 8 hours

Infants up to 6 kg of body weight:
25-50 mg every 8 hours

Infants 6-8 kg of body weight:
50-100 mg every 8 hours

Infants and children 8-20 kg of body weight:

6.7-13.3 mg/kg every 8 hours

Gonorrhea: 3 g as a single dose with 1 g of probenecid.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Zmox for as long as your 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 a forgotten dose.

- 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 taken too much of this medicine. Do this even if there is no signs of discomfort or poisoning. You may need urgent medical attention. Symptoms of overdosage include upset stomach (nausea, vomiting or diarrhoea) or crystals in the urine, which may be seen as cloudy urine, or problems passing urine.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you. Never take only part of capsules and suspension

Adequate fluid intake and urine output are essential during treatment.

Tell all the doctors and pharmacists treating you that you are taking Zmox.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless

advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Zmox to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

To be sold by Retail on the prescription of a Registered Medical Practitioner only. Watch out for important symptoms if you develop any of these symptoms after you start taking Amoxicillin, get doctor straight away include skin rash or swelling of the face or neck

Side effects

Like all medicines, Zmox can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

- Diarrhea and nausea
- Urticarial rashes, fever, joint pains
- Decreasing blood cell count
- Low platelet count
- Skin allergy and skin itching
- Headache, feeling of tiredness, tongue is swelling and changes color
- Inflammation of mouth
- Inflammation of the interstitial tissue of the kidney
- Inflammation of the liver and

Stop taking Zmox and contact your doctor immediately if you experience any of the following:

- Serious allergic reactions such as Drug Reaction and Eosinophillia 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.

Z Mox may cause severe allergy and serious skin reactions. Stop using Z Mox 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 nptra.moh.gov.my (Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of Zmox

- Storage

Keep out of the reach and sight of children.

Do not use Amoxicillin after the expiry date which is stated on the carton and blister foil after the EXP.

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

For capsules: Store in a dry place below 30°C

For oral suspension:

Store at or below 30°C

Once reconstituted, store at or below 30°C and to be used within 14 days.

- 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

Z Mox Capsules 250MG:

Maroon /yellow, Size “1” hard gelatin capsules filled with white to off white granular powder and imprinted with “A” on maroon cap and “85” on yellow body with black ink.

Z Mox Capsules 500 MG:

Orange /orange, size “0” hard gelatin unprinted capsules, filled with white to off white granular powder.

Z Mox Oral Suspension 125MG/5ML: White to off-white granular powder free from foreign particles. After reconstitution: An orange colour suspension with sweet taste and orange flavor

Z Mox Oral Suspension 250MG/5ML: White to off-white granular powder free from foreign particles. After reconstitution: An orange colour suspension with sweet

taste and orange flavor

- Ingredients

For capsules:

- Active ingredients: Amoxicillin trihydrate
- Inactive ingredients: Cellulose microcrystalline and Magnesium Stearate

For oral suspension:

- Active ingredients: Amoxicillin
- Inactive ingredients: Colloidal Anhydrous Silica, Sodium Citrate, Disodium Edetate, Sodium Benzoate, Xanthan gum, Sunset yellow supra, Orange flavour Capsaroma and Sugar.

- MAL number(s):

Z Mox Capsules 250MG:
MAL09051607AZ

Z Mox Capsules 500MG:
MAL09042401AZ

Z Mox Oral Suspension 125MG/5ML:
MAL13015035AZ

Z Mox Oral Suspension 250MG/5ML:
MAL09042411AZ

Manufacturer

Aurobindo Pharma Limited, (Unit XII)
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Product Registration Holder

UNIMED SDN BHD
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