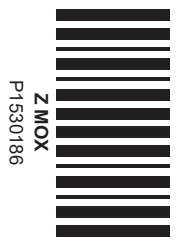

Z MOX

Z MOX 250
(Amoxicillin capsules 250 mg)

Z MOX 500
(Amoxicillin capsules 500 mg)

Z MOX 125
(Amoxicillin for oral suspension USP 125 mg/5 ml)

Z MOX 250
(Amoxicillin for oral suspension USP 250 mg/5 ml)

Description and Composition:

Z MOX 250 mg Capsule
Maroon/Yellow, size "1" hard gelatin capsule filled with white to off white granular powder and imprinted with "A" on maroon cap and "85" on yellow body with black ink.
Each capsule contains: Amoxicillin Trihydrate equivalent to Amoxicillin 250mg.

Z MOX 500 mg Capsules
Orange/Orange, size '0EL' hard gelatin unprinted capsules, filled with white to off white granular powder.
Each capsule contains: Amoxicillin Trihydrate equivalent to Amoxicillin 500mg.

Z MOX 125 oral suspension
White to off-white granular powder free from foreign particles.
After reconstitution: An orange colour suspension with sweet taste and orange flavour.
Each 5 ml (After reconstitution) contains: Amoxicillin equivalent to anhydrous Amoxicillin 125 mg

Z MOX 250 oral suspension
White to off-white granular powder free from foreign particles.
After reconstitution: An orange colour suspension with sweet taste and orange flavour.
Each 5 ml (After reconstitution) contains: Amoxicillin equivalent to anhydrous Amoxicillin 250 mg

Direction for mixing/dilution: Tap the bottle until the powder flows freely. Add approximately 2/3 of the total amount of water for reconstitution and shake vigorously to suspend powder. Add remaining water up to the mark on the bottle and again shake vigorously.

Pharmacodynamics
Amoxicillin is highly potent, broad-specturm penicillin with a particularly rapid once and a broad spectrum of action. Like other penicillin, it acts by inhibiting cell wall synthesis. Thanks to its broad action spectrum, it is active against both gram-positive and gramnegative micro-organisms. Clinically relevant gram-negative pathogen covered by amoxicillin are Escherichia coli, Proteus mirobilis, Salmonella, Shigella, Campylobacter, Hemophilus influenza, Bordetella pertussis as well as Leptospira and Chlamydia. Other micro-organisms responding to amoxicillin include all those susceptible to penicllin G, e.g. group A, B, C, G, H, L and M streptococci, Streptococcus pneumoniae, non-penicillinaseproducing Staphylococcus aureus Neisseri, Erysipelothrix rhusiopathiae, Corynebacterium, Bacillus anthracis, Actinomycetes, streptobacilli, spirillium minus, Pasteurella multocida, Listeria and Spirochetal organisms (Leptospira, Treponema, Borrelia and other Spirochetes) as well as numerous anaerobic organisms (among them peptococci, peptostreptococci, Clostridia and Fuso-bacteria).

Pharmacokinetics
The absorption of amoxicillin is unaffected by meals. The drug is almost completely absorbed from the small intestine. Peak serum levels are reached within 1 to 2 hours after ingestion. Amoxicillin readily distributes in body tissues and fluids including the sputum and purulent bronchial secretions. If liver function is intact, high biliary drug concentrations are reached. Amoxicillin is eliminated at a half-life of approximately 1 to 2 hours. Elimination is predominantly renal. More that half of the oral dose is excreted with the urine in a therapeutically active form.

Indications
Z MOX is useful in the treatment of infections caused by amoxicillin susceptible organisms:
Respiratory tract infections
- Upper airways and ENT infections
- Lower airways infections, e.g. acute and chronic bronchitis, pneumonia, lung abscess pertussis (incubation period and early stages)

Urogenital infections
- Acute and chronic pyelonephritis, pyelitis, prostatitis, epididymitis
- Cystitis, urethritis, asymptomatic bacteriuria during pregnancy
- Gonorrhoea

Gynecologic infections (septic abortion, adnexitis, endometritis, etc.)

Gastro-intestinal infections
- Typhoid fever, paratyphoid, particularly if complicated by septicemia (in combination with an aminoglycoside antibiotic); control of salmonella carriers
- Shigellosis

Infections of the biliary system (cholangitis, cholecystitis)

Skin and soft tissue infections
Leptospirosis
Acute and latent listeriosis
Unless parenteral treatment (e.g. with ampicillin) is required, Z MOX is also active in the conditions below:
- Short-term (24 to 48 hrs) prophylactic treatment of patients undergoing surgery (e.g. in the oral cavity)
- Endocarditis, e.g. enterococcal endocarditis (alone or in combination with an aminoglycoside antibiotic)
- Bacterial meningitis (pending the outcome of susceptibility test; particularly in children)
- Septicemias caused by amoxicillin-susceptible pathogens.

Infections caused by pathogens with established penicillin G susceptibility should preferentially be treated with penicillin G.

Recommended dose
Z MOX is stable in the presence of gastric acid and may be given before or after food. Adults, children 20 kg of body weight and above: 250 - 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 of body weight every 8 hours Gonorrhoea: 3 g as a single dose with 1 g of probenecid.
Treatment should be continued for a minimum of 48 - 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

Mode of administration
Oral

Contraindication
Known and suspected hypersensitivity to penicillin. Potential cross allergy should be considered in patients with cephalosporin hypersensitivity.
Because of the increased incidence of side effects (rashes) amoxicillin should not be administered to patients with mononucleosis and lymphatic leukemia.
Severe gastro-intestinal infections with persistent diarrhea or vomiting should not be treated with oral amoxicillin because of the risk of reduced absorption.
Antibiotics have no place in trivial infections.
Special caution should be exercised in patients with allergic diatheses or bronchial asthma and hay fever.

Warning and precautions
Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with Z Mox, careful inquiry should be m ade concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Z Mox must be discontinued immediately and appropriate alternative therapy instituted.

If allergic reactions occur, the drug should be discontinued and the usual treatment with epinephrine, antihistamines and corticosteroids should be instituted. If maculopopular amoxicillin rashes develop, treatment should be confined to life-threatening conditions and patients should be carefully monitored.

Adequate fluid intake and urine output are essential during treatment. Patients with cholangitis and cholecystitis should only be prescribed antibiotics, if the condition is of minor severity and unassociated with cholestasis.

During high-dose long-term treatment liver function should be monitored; urinalysis and renal function tests should be ordered in patients with pre-existent renal damage and in those developing skin rashes. Blood counts should be monitored to identify antibody-related reactions of the hematopoietic system and hemolytic anemia.

During long-term treatment attention should be paid to the potential overgrowth of resistant micro-organisms and fungi. Secondary infections should be treated by suitable measures. Severe and persistent diarrhea should prompt suspicion of antibiotic-induced pseudo membranous colitis (blood-streaked, mucoid, watery diarrhea; dull diffuse or colicky abdominal pain; fever and occasional tenesms), which may be life-threatening. In pertinent cases Z MOX should immediately be with drown and treatment specific for the offending organism (e.g. oral Vancomycin) should be instituted. Antiperistaltic drugs are contra-indicated.

In patients to be treated for gonorrhea who are suspected of having primary syphilitic lesions treatment should be preceded by dark field examinations. All other patients with suspected co-existing syphilis should be followed up serologically for at least 4 months.

Interactions with other medicaments
Concomitant ingestion of allopurinol may promote the occurrence of skin rashes. The underlying mechanisms are still poorly understood. As penicillin like amoxicillin only act on proliferating microorganisms, they should not be combined with bacteriostatic antibiotics, e.g tetracycline's and chloramphenicol. If suggested by the outcome of susceptibility tests, combinations with other bactericidal antibiotics (cephalosporins, aminoglycosides) may be used.

The concomitant administration of probenecid (e.g. 0.5 g four times a day orally; contraindicated in children below age 2 years) produces sustained and higher plasma levels by suppressing renal elimination. Conversely, tissue distribution and diffusion of Z MOX may be reduced by probenecid. Like other antibiotics, aminopenicillins may rare ly reduce the efficacy of oral contraceptives.

Concomitant antacid intake reduces amoxicillin absorption. Nonenzymatic urinary glucose tests may be false positive. Urobilinogen tests may also be impaired.

Pregnancy and lactation
There is no current evidence to suggest any embryotoxic, teratogenic or mutagenic effects of Z MOX during pregnancy. It should, however, be borne in mind that amoxicillin diffuses into breast milk.

Side effects
Occasional transient side effects are mostly gastro-intestinal (nausea and diarrhea). Owing to the better absorption of amoxicillin they are, however, less commonly seen than during ampicillin treatment. In patients developing diarrhoea during treatment pseudomembranous colitis should be considered.

A/s: 210 x 300 mm ■ Black Booklet Size: 35 x 60 mm

AUROBINDO Packaging Development		Product Name	Component	Item Code	Date & Time
		Z MOX	Leaflet	P1530186	26.07.2022 & 05.00 pm
		Country	Version No.	Reason Of Issue	Reviewed / Approved by
		Malaysia	06	Submission	
Team Leader	Kiran K	Dimensions (mm)	Colours		
Initiator	Shirisha	210 x 300 mm	No Of Colours: 01		
Artist	Sree Designers	Pharma Code: 30186			
Additional Information: Supersedes: P1516911					

30186

Adverse Effect / Undesirable Effects
Skin and subcutaneous tissue disorders: Frequency 'very rare': Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS).

Rarely, hypersensitivity reactions like urticarial rashes, fever, joint pain, erythema multiforme, exfoliative dermatitis, angioneurotic edema a dermatologic problems, e.g. thrombocytopenia, agranulocytosis, leucopenia and eosinophilia are seen. These usually run a mild course and generally subside within a few days.

Like all other penicillins, Z MOX may exceptionally cause severe systemic reactions (anaphylactic shock).

Exfoliative dermatitis and erythema multiforme have been described in some cases. Like other penicillin, amoxicillin may cause headache, fatigue, glossitis, stomatitis, fever, joint pain, angioneurotic edema or interstitial nephritis.

Patients treated for typhoid fever, leptospirosis or syphilis may develop jarisch-Herxheimer's reaction secondary to bacterial lysis.

As with all penicillins producing high plasma levels, patients with epilepsy or meningitis and reduced renal function run an increased risk of developing neurotoxic manifestations (seizures). Minor transient elevations of serum transaminases (SGOT and SGPT) have occasionally been seen.

Symptoms and Treatment of over dose
Gastrointestinal effects such as nausea, vomiting and diarrhoea may occur and should be treated symptomatically with attention to the water/electrolyte balance. Amoxicillin crystalluria, in some cases leads to renal failure Amoxicillin may be removed from the circulation by haemodialysis.

Storage condition
For capsules:
Store in a dry place below 30^{o}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

Shelf life
Z MOX 250 mg Capsules: 36 months
Z MOX 500 mg Capsules: 36 months
Z MOX 125 mg Oral Suspension: 36 months
Z MOX 250 mg Oral Suspension: 24 months

Nature and contents of container
Z MOX 250 and 500: Blister of 10 Capsules, 10 such blisters are packed in a printed carton along with the package insert.
Z MOX 250 and 500: Blister of 10 capsules, 100 such blister are packed in a E-Flute box along with the pack insert.
Z MOX oral suspension 125 mg/5ml: – 60 & 100ml amber coloured glass bottle is packed in a printed carton along with the package insert.
Z MOX oral suspension 250 mg/5ml: – 60 & 100ml amber coloured glass bottle is packed in a printed carton along with the package insert.

Manufacturer address:

AUROBINDO

Aurobindo Pharma Limited,
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Bachupally, Bachupally Mandal,
Medchal-Malkajgiri District, Hyderabad,
Telangana State, 500 090, India.

PRODUCT REGISTRATION HOLDER AND IMPORTED BY:
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NO.53, Jalan Tembaga SD5/2B Bandar
Sri Damansara 52200 Kuala Lumpur,
Malaysia

DATE OF REVISION: October 2023.

P1530186