

COMPOSITION

AMX 250 Capsule: Each capsule contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 250 mg.

AMX 500 Capsule: Each capsule contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 500 mg.

AMX Powder for Suspension: After reconstitution, each 5 ml suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 125 mg.

AMX DS Powder for Suspension: After reconstitution, each 5 ml suspension contains Amoxicillin Trihydrate BP equivalent to Amoxicillin 250 mg.

PHARMACOLOGY

AMX (Amoxicillin) is a broad spectrum penicillin. It is effective against a wide range of Gram-positive and Gram-negative bacteria. Amoxicillin is stable in the presence of gastric acid and is rapidly absorbed after oral administration. After an oral dose, peak plasma concentration of Amoxicillin is reached within 1 to 2 hours. Amoxicillin is widely distributed at varying concentration in body tissues and fluids.

INDICATION

Amoxicillin is indicated in the treatment of infections due to susceptible β -lactamase negative strains of microorganisms. These infections include Ear, Nose and Throat Infections (i.e. Otitis media, Sinusitis, Tonsillitis, Pharyngitis, Laryngitis), Lower Respiratory Tract Infections (i.e. Pneumonia, Acute and Chronic Bronchitis, Lung Abscess, Empyema, Bronchiectasis), Skin and soft tissue infections (i.e. Cellulitis, Carbuncles, Furunculosis, Infected Wounds, Abscess), Genito-urinary Tract infections (i.e. Pyelonephritis, Cystitis and urethritis) and venereal disease (i.e. acute uncomplicated gonorrhoea). In dental abscess, it is used as short-term therapy.

It is also indicated in combination with Clarithromycin and Lansoprazole (as triple therapy), for the treatment of patients with *H. pylori* infection and duodenal ulcer disease and to reduce the risk of duodenal ulcer recurrence.

DOSAGE AND ADMINISTRATION

Adult: 250 mg three times daily, increasing up to 500 mg three times daily for severe infections.

Children (up to 10 years of age): 125 mg three times daily, increasing up to 250 mg three times daily for severe infections. Severe or recurrent purulent respiratory infection, 3 gm every 12 hours.

Otitis media: Recommended dose is 1 gm three times daily for adult and 40 mg/kg body weight daily in 3 divided doses for children (max. 3 gm daily).

Pneumonia: Recommended dose is 500-1000 mg three times daily.

Dental abscess: Recommended dose is 3 gm, repeated after 10-12 hours.

Urinary tract infections: Recommended dose is 3 gm, repeated after 10-12 hours.

Gonorrhoea: Single dose of 2-3 gm with Probenecid 1 gm is recommended (Probenecid is contraindicated in children under 2 years).

In renal impairment, it may be necessary to reduce the total daily dosage.

Reconstituted suspension can be administered by adding the required amount of suspension to milk, fruit juice, water. These preparations should be taken immediately.

CONTRAINDICATION

Amoxicillin is contraindicated in patients who have experienced a serious hypersensitivity reaction (e.g., anaphylaxis or Stevens-Johnson syndrome) to Amoxicillin or to other β -lactam antibiotics (e.g., penicillins and cephalosporins).

WARNING AND PRECAUTION

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy including Amoxicillin. Clostridium difficile associated diarrhea (CDAD) has been reported. Prescribing Amoxicillin in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur, Amoxicillin should be discontinued and appropriate therapy should be instituted. A high percentage of patients with mononucleosis who receive Amoxicillin develop an erythematous skin rash. Thus, Amoxicillin should not be administered to patients with mononucleosis.

SIDE EFFECTS

Side effects are mild and transient in nature. This may include diarrhoea, indigestion or occasionally rash. Pseudo-membranous colitis has been reported rarely.

USE IN PREGNANCY AND LACTATION

US FDA pregnancy category of Amoxicillin is B. There is however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, This drug should be used during pregnancy only if clearly needed. Amoxicillin has been shown to be excreted in human milk. So, caution should be exercised when Amoxicillin is administered to a lactating mother.

USE IN CHILDREN ADOLESCENTS

Because of incompletely developed renal function in neonates and young infants, the elimination of Amoxicillin may be delayed. Dosing of Amoxicillin should be modified in paediatric patients 12 weeks or younger (≤ 3 months).

DRUG INTERACTION

Concurrent use of Amoxicillin and Probenecid may result in increased and prolonged blood levels of Amoxicillin. Amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives. The concurrent administration of Allopurinol and Amoxicillin increases the incidence of rashes. Abnormal prolongation of prothrombin time has been reported in patients receiving Amoxicillin and oral anticoagulants. Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the bactericidal effects of penicillins. Following administration of Amoxicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone, and estradiol has been noted.

OVERDOSAGE

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required.

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

AMX 250 Capsule: Each box contains 100 capsules in Alu-PVC blister pack.

AMX 500 Capsule: Each box contains 50 capsules in Alu-PVC blister pack.

AMX Powder for Suspension: Each amber glass bottle contains dry powder to reconstitute 100 ml suspension.

AMX DS Powder for Suspension: Each amber glass bottle contains dry powder to reconstitute 100 ml suspension.