

AMX

Amoxicillin

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 g three times daily for adult and 40 mg/kg body weight daily in 3 divided doses for children (max. 3 g 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 then be taken immediately.

CONTRAINDICATION

Amoxicillin is contraindicated in penicillin hypersensitive patients.

WARNING AND PRECAUTION

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.

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 are, 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

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.

OVERDOSE

STORAGE CONDITION

Keep in a cool & dry place below 30°C temperature, protected from light and 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.

Manufactured by:

NIPRO JMI Pharma Ltd.

Chauddagram, Cumilla, Bangladesh.