

## MAXI-500

### Amoxicillin Capsules BP

#### COMPOSITION :

Each hard gelatin capsule contains :  
Amoxicillin Trihydrate BP 500 mg  
eq. to Amoxicillin  
Excipients q.s.  
Approved colour used in capsule shells.

#### DESCRIPTION:

Amoxicillin is broad-spectrum penicillin derived from 6-aminopenicillanic acid. It is active against most common pathogens encountered in clinical practice. It acts by selectively inhibiting the synthesis of protective cell wall of bacteria. It acts by acylation of membrane-bound transpeptidase enzymes.

#### Indication:

Indicated in the treatment of infections due to susceptible strains of designated microorganisms in the conditions below:  
[Infections of the ear, nose, and throat due to *Staphylococcus* sp., *Staphylococcus pneumoniae*, *Streptococcus* sp., or *E. coli*.  
Infections of the genitourinary tract due to *E. coli*, *P. mirabilis*, or *E. faecalis*.  
Infections of the skin and skin structure due to *Staphylococcus* sp., *Streptococcus* sp., or *E. coli*.  
Infections of the lower respiratory tract due to *Staphylococcus* sp., *Streptococcus* sp., *Streptococcus pneumoniae*, or *H. influenzae*.  
Gonorrhoea, acute uncomplicated (ano-genital and urethral infections) due to *N. gonorrhoeae* (males and females).

#### CONTRA-INDICATIONS:

Hypersensitivity to quinolones, pregnancy, lactation, children below 18 years. Cross-sensitivity occurs among penicillins and cephalosporins.

#### DOSAGE AND ADMINISTRATION:

Adults: 250-500 mg 3 times daily,  
Children up to 10 years: 125-250 mg every 8 hrs.  
Children <20kg body weight: 20-40 mg/kg daily in 3 divided doses has been suggested.  
A single dose of 3g (often with 1g of probenecid) for treatment of gonorrhoea  
A dose of 3gm repeated once after 8 or 10 to 12 hours may be used for dental abscesses or uncomplicated acute urinary-tract infections, respectively.  
For the prophylaxis of endocarditis in susceptible patients amoxicillin 3gm is given about 1 hour before procedures such as dental extractions.  
A high dose regimen of amoxicillin 3gm twice daily may be used in-patients with severe or recurrent infections of the respiratory tract. If necessary, children aged 3

to 10 years with otitis media may be given 750mg twice daily for two days.

#### DRUG INTERACTIONS:

**Allopurinol:** A significant increase in skin rashes is observed when allopurinol and amoxicillin are given concurrently.  
**Bacteriostatic drugs:** like chloramphenicol, erythromycin and tetracyclines may reduce the bactericidal action of amoxicillin.

#### ADVERSE-EFFECTS:

Adverse effects are usually of a mild and transitory nature, eg diarrhoea, indigestion or an occasional rash, either urticarial, which suggests penicillin hypersensitivity, or erythematous. An erythematous rash may occur in patients with infectious mononucleosis. In either case, treatment should be discontinued.

#### WARNING & PRECAUTIONS:

Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. If an allergic reaction occurs, amoxicillin should be discontinued and appropriate alternative therapy instituted.

**Pregnancy:** Amoxicillin at doses 10 times the human doses did not cause any adverse effects on reproduction and fertility in rats and mice. Amoxicillin can be used safely throughout pregnancy at the normal adult doses.

**Breast-feeding:** Amoxicillin is excreted into breast milk in small amounts. The potential risk is for sensitization and skin rash in the child.

**Use in renal impairment:** Dosage of Amoxicillin should be modified in patients with severe renal impairment, by increasing the intervals between doses.

**Use in elderly:** No special precautions required except when renal impairment is present.

#### OVERDOSAGE:

Symptoms of overdosage could be related to the gastrointestinal tract: Vomiting, nausea and diarrhoea. These should be treated symptomatically. Allergic reactions may occur and should be treated symptomatically.

If diarrhoea persists pseudomembranous colitis should be considered as a possibility. Apart from supportive therapy, severe cases should be treated with vancomycin orally 125 to 500 mg every 6 hours for 5 to 10 days. Amoxicillin may be removed from circulation by haemodialysis.

**Storage conditions:** Store below 30°C, Protected from light & moisture. Keep the medicine out of reach of children.

**PRESENTATION:** 10 blisters of 10 capsules packed in a carton (10x10's).

Manufactured in India by:

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