

ANTALPEN[®]

(Ampicillin 500mg Capsules)

Composition

Each Capsule contains 500 mg of ampicillin as ampicillin trihydrate B.P.

Indications

Ampicillin (ANTALPEN[®]) is a broad-spectrum penicillin, indicated for the treatment of a wide range of bacterial infections caused by Ampicillin-Sensitive organisms. Such indications include infections of the upper and lower respiratory tract, genito-urinary tract and the gastro-intestinal tract. Specific indications include ear and soft tissue infections and gonorrhoea.

Posology and Method of Administration

All recommended dosages are a guide only. In severe infections, the above dosages may be increased at the direction of the physician.

Ampicillin should be taken with a full glass of water, one-half hour before or two hours after meals.

For oral administration only.

Usual adult dosage

Ear, nose and throat infections:	250 mg four times a day
Bronchitis :	Routine therapy: 250 mg four times daily High dose therapy: 1 g four times daily
Pneumonia :	500 mg four times daily.
Urinary tract infections:	500 mg three times daily
Gastro-intestinal infections:	500 - 750 mg three to four times daily
Enteric fevers:	Acute: 1-2 g four times daily for two weeks Carriers: 1-2 g four times daily for 4 to 12 weeks
Gonorrhoea:	2 g orally with 1g probenecid as a single dose. Repeated doses are recommended for the treatment of females.

Usual dosage for the elderly:

As for adults; reduced doses may be required in those with impaired renal function.

Usual Children's dosage (Under 10 years):

Half adult routine dosage.

Renal Impairment :

In severe renal impairment (i.e., Creatinine clearance < 10 mL / min), reduction in dose or extension of the dose interval should be considered. In patients undergoing dialysis, an additional dose should be administered after dialysis.

Contraindications

Ampicillin is contraindicated in patients with hypersensitivity to penicillins, ampicillin, or cephalosporins and in infections caused by penicillinase-producing organisms.

Special Warnings and Precautions for Use

- Before initiating therapy with ampicillin, careful enquiry should be made concerning previous hypersensitivity reactions to beta-lactam antibiotics.
- Serious and occasionally fatal hypersensitivity reactions (anaphylaxis) have been reported in patients receiving beta-lactam antibiotics. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of beta-lactam hypersensitivity.
- Prolonged use of an anti-infective may occasionally result in the development of super-infection due to organisms resistant to that anti-infective e.g. *Candida* or *Pseudomonas*.
- Care should be taken with patients with renal impairment and dose adjustment may be required.
- Care is necessary when treating spirochaete infections particularly Syphilis.

Drug Interactions

Ampicillin may reduce the efficacy of oral contraceptives and patients should be warned accordingly.

Uricosurics: excretion of penicillin is decreased, giving an increased risk of toxicity e.g. Probenecid and sulfinpyrazon.

Allopurinol increases ampicillin induced skin reactions.

Anti-coagulants: INR can be altered by the administration of Ampicillin while on Warfarin and Phenindione.

Vaccines: The efficacy of Oral Typhoid Vaccine may be reduced when ampicillin is coadministered.

Cytotoxics: the excretion of methotrexate is reduced.

Chloroquine: absorption of ampicillin is reduced when taken concomitantly with chloroquine. There may be an interaction between other bacteriostatic antibacterials such as erythromycin, chloramphenicol and tetracycline may interfere with the bactericidal action of ampicillin.

As **probenecid** prolongs the half-life of this penicillin, it may be used therapeutically for this purpose. Ampicillin may interfere with some diagnostic tests e.g. tests for urinary glucose using copper sulphate, direct anti-globulin (Coombs' test) and some tests for urinary or serum proteins. Tests using bacteria, e.g. the Guthrie test for phenylketonuria using *Bacillus Subtilis* organisms, could also be affected while patients are taking penicillins.

Pregnancy and Lactation

Pregnancy:

Animal studies with ampicillin have shown no teratogenic effects. However, penicillin should be used during pregnancy only if clearly needed.

Lactation:

Ampicillin can pass into breast milk and may harm a nursing baby. Do not use this medication without telling your doctor if you are breast-feeding a baby.

Side Effects

Side-effects, as with other penicillins, are uncommon and mainly of a mild and transitory nature.

Occasionally, gastro-intestinal disturbances, nausea, vomiting and diarrhea or haemorrhagic colitis or pseudomembranous colitis may occur.

Erythematous maculo-papular rashes, sore mouth and sore, black, hairy tongue have occurred. If a rash occurs, treatment should be discontinued.

Angioedema and anaphylaxis have occasionally occurred.

There have been reports of haemolytic anaemia, thrombocytopenia, leucopenia, neutropenia and coagulation disorders.

Prolongation of bleeding time and prothrombin time have also been reported rarely.

Particularly with high doses or in renal impairment, CNS toxicity including convulsions have occurred; with prolonged use paraesthesia.

Nephropathy and interstitial nephritis has been reported.

Hepatic effects: As with other beta-lactam antibiotics, hepatitis and cholestatic jaundice have been reported rarely.

As with most other antibiotics, a moderate and transient increase in transaminases has been reported.

Overdose

Gastrointestinal effects such as nausea, vomiting and diarrhea may be evident and should be treated symptomatically. Ampicillin may be removed from the circulation by hemodialysis.

Storage

- Store in a cool and dry place, below 25 °C.
- Store away from heat and direct light.
- Keep out of the reach of children.

Shelf Life

3 Years.

How supplied

ANTALPEN[®] 500 mg Capsules, are supplied in a box of 20 capsules