AMOXICILLIN

Amoxicillin Capsules B.P. 500 mg

Composition:

Each hard gelatin Capsule contains : Amoxicillin Trihydrate B.P.

eq. to Amoxicillin 500 mg.

Excipents Q.S.

Approved Colours used in empty capsule shell

PHARMACOLOGICAL ACTION :

Amoxicillin [Amoxicillin Trihydrate] a semisynthetic penicillinase susceptible penicillin, an analogue of ampicillin, with a broad spectrum of in-vitro bactericidal activity against many gram-positive and gram-negative microorganisms.

In vitro sensitivity does not necessarily imply in-vivo efficacy.

Resistant strains: Enterobacter, Pseudomonas, Klebsiella, Serratia, Acinetobacter and indole-positive Proteus.

Pharmacokinetics:

Amoxicillin [Amoxicillin Trihydrate] is resistant to inactivation by gastric acid and may be given without regard to meals. It is rapidly and completely absorbed after oral administration. Amoxicillin [Amoxicillin Trihydrate] is not highly protein-bound. Orally administered doses of 250 mg and 500 mg Amoxicillin [Amoxicillin Trihydrate] capsules result in average peak blood levels one to two hours after administration in the range of 3.5 mcg/mL to 5.0 mcg/mL and 5.5 mcglmL to 7.5 mcg/mL respectively. Detectable serum levels are observed up to 8 hours after an orally administered dose of Amoxicillin [Amoxicillin Trihydrate]. It diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid except when meninges are inflamed. The half-life of Amoxicillin [Amoxicillin Trihydrate] is 1 to 1.5 hours. Approximately 60 percent of an orally administered dose of Amoxicillin [Amoxicillin Trihydrate] is excreted unchanged in the urine within six to eight hours by glomerular filtration and tubular secretion is removed by haemodialysis. High concentrations have been reported in bile; some may be excreted in faeces.

INDICATIONS :

It is indicated in the treatment of infections due to susceptible non-penicillinase producing strains of the following:

-Infections of the ear, nose and throat due to Streptococci, Pneumococci, non-penicillinase producing Staphylococci and H. influenzae.

- Infections of the genito-urinary tract due to E. coli, Proteus mirabilis and Streptococcus faecalis.
- Infections of the skin and soft-tissues due to Streptococci, susceptible Staphylococci and E. coli.
- Infections of the lower respiratory tract due to Streptococci, Pneumococci, non-penicillinase producing Staphylococci and H. influenzae.
-Gonorrhoea, acute uncomplicated ano-genital and urethral infections due to N. gonorrhea (males and females).

CONTRA-INDICATIONS:

A history of allergic reaction to any of the penicillins **or** cephalosporins is a contra-indication. It is also contra-indicated in infectious mononucleosis. It is also contra-indicated in babies born of hypersensitive mothers in the neonatal period.

Patients with lymphatic leukemia and patients with hyperuricaemia being treated with allopurinol may also be at an increased risk of developing skin rashes.

WARNINGS:

When administered to a patient with penicillin sensitivity anaphylactic shock may occur. Adrenaline, corticosteroids and antihistamines should be used to treat anaphylaxis. Use with caution in patients with known history of allergy.

DOSAGE AND DIRECTIONS FOR USE :

E.N.T. Infections, UTI and skin and Soft-tissue Infections

Adults: 250 mg every 8 hours.

Children: 20 mg/kg/day in divided doses every 8 hours. Children weighing 20 kg or more should be dosed according to the adult recommendations.

In severe infections or those caused by less susceptible organisms: 500 mg every 8 hours for adults and 40 mg/kg/day in divided doses every 8 hours for children may be needed. Gonorrhoea

Adults: 3 grams as a single oral dose, with probenecid 1 gm.

Prepubertal children: 50 mg/kg Amoxicillin [Amoxicillin Trihydrate] combined with 25 mg/kg probenecid as a single dose. Since probenecid is contraindicated in children under 2 years, this regimen should not be used in these cases or as directed by the physician.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Side-effects

Sensitivity reactions are more likely to occur in individuals who have previously demonstrated hypersensitivity to penicillins and in those with a history of allergy, asthma, hay fever or urticaria. The hypersensitivity reactions reported are Erythematous maculopapular rashes, urticaria, fever and joint pains. Anaphylactic shock may occur.

Gastrointestinal

Nausea, heartburn, vomiting and diarrhoea.

Liver :

A moderate rise in serum glutamic oxaloacetic transaminase (SCOT) has been noted, but the significance of this finding is unknown.

Haemic and Lymphatic Systems :

Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and granulocytopenia have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.

Central Nervous System :

Reversible hyperactivity, agitation, anxiety, insomnia, confusion, behavioural changes and/or dizziness have also been reported.

Others

A sore mouth or tongue and a black hairy tongue have been reported. Allergic reactions which may include exfoliative dermatitis, other skin rashes, interstitial nephritis and vasculitis, may occur.

Precautions :

- Before initiating therapy with any penicillin, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If any allergic reaction occurs, appropriate therapy should be instituted and discontinuance of Amoxicillin [Amoxicillin Trihydrate] therapy considered.
- Periodic assessment of renal, hepatic and haematopoetic function should be made during prolonged therapy with Amoxicillin [Amoxicillin Trihydrate] Capsules.
- Pseudomembranous colitis has been reported.
- The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Enterobacter, Pseudomonas or Candida), the medicine should be discontinued or appropriate therapy should be instituted.
- Care should be taken when treating patients with syphilis, as the Jarisch-Herxheimer reaction may occur and may shortly alter starting treatment. This reaction, manifesting as fever, chills, headache and reactions at the site of the lesion, can be dangerous in cardiovascular syphilis or where there is a serious risk of increased local damage such as with optic atrophy.
- Care should be taken when high doses are given to patients with renal impairment (because of the risk of neurotoxicity) or congestive heart failure.

Interactions

It may decrease the efficacy of oral contraceptives and may cause increased breakthrough bleeding. Probenecid can delay the excretion of Amoxicillin [Amoxicillin Trihydrate] Capsules when given concurrently.

Usage In Pregnancy

Animal reproduction studies have failed to demonstrate a risk to the foetus and there are no adequate and well controlled studies in pregnant women.

Known Symptoms of Overdosage And Particulars Of Its Treatment:

See side-effects. Treatment is symptomatic and supportive. In the event of overdosage, Amoxicillin [Amoxicillin Trihydrate] can be removed by haemodialysis.

PRESENTATION:

1 x 10 Capsules.

STORAGE INSTRUCTIONS:

Store in cool and dry place. Protect from light and moisture

Keep medicine out of reach of children.