



S P A R S H B I O - T E C H P V T . L T D .

PHARMACEUTICAL MANUFACTURER & EXPORTERS

PLOT NO.1, SURVEY NO. 242/243/244, LAKHABAVAD, JAMNAGAR – 361 006 (INDIA)

1.6.3. PATIENT INFORMATION LEAFLET (PIL)

Attached Hereafter

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For the use of registered medical practitioners or hospital/ Laboratory.

SPAMOX

AMOXICILLIN CAPSULES, AMOXICILLIN DISPERSIBLE TABLETS & AMOXICILLIN ORAL SUSPENSION

DESCRIPTION: Amoxicillin is a semi synthetic antibiotic, and analogue of Ampicillin with a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms. Chemically empirical formula is (6R)-6-[Q-D-(4-hydroxyphenyl glycyamino) penicillanic acid Trihydrate] and the molecular weight is 419.45.

CLINICAL PHARMACOLOGY: Amoxicillin is stable in the presence of gastric acid and may be given without regards to meals. It is rapidly absorbed after oral administration. Amoxicillin diffuses readily into most body tissues and fluids with the exception of the brain and spinal fluid, except when meninges are inflamed. The half life of amoxicillin is 61.2 minutes. Most of the amoxicillin is excreted unchanged in urine; excretion can be delayed by concurrent administration of probenecid. In blood serum, amoxicillin is approximately 20% protein bound as compared to 60% of penicillin G.

Orally administered doses of 250mg and 500mg amoxicillin capsules result in average peak blood levels 1 to 2 hours after administration in the range of 3.5mcg/ml to 5.0 mcg/ml and 5.5 mcg/ml to 7.5 mcg/ml respectively.

Detectable serum levels are observed upto 8 hours after and oral administered dose of Amoxicillin. Following a 1g dose and utilizing a special skin window technique to determine levels of antibiotic, it was noted that therapeutic levels were found in the intestinal fluids. Approximately 60% of an orally administered dose of amoxicillin is excreted in the urine within six to eight hours. Amoxicillin exerts bactericidal action against susceptible organisms during the stage of active multiplication.

Microbiology: Amoxicillin is similar to Ampicillin in its bactericidal action against susceptible organisms during the stage of active multiplication. It acts through the inhibition of cell wall mucopolypeptides. Amoxicillin has been shown to be active against most strains of the following microorganisms, both invitro and in clinical infections as described in INDICATION AND USAGE.

Aerobic Gram-positive Microorganisms:

Enterococcus faecalis.

Staphylococcus spp. (lactamase-negative strains only)

Streptococcus pneumoniae.

Streptococcus spp (and haemolytic strains only)

Staphylococci, which are susceptible to Amoxicillin but resistant to methicillin/oxacillin, should be considered as resistant to amoxicillin.

Aerobic Gram-negative Microorganisms:

Escherichia coli (lactamase- negative strains only)

Haemophilus influenzae (lactamase- negative strains only)

Neisseria gonorrhoeae (lactamase- negative strains only)

Proteus mirabilis (lactamase- negative strains only)

Helicobacter pylori.

INDICATIONS

Amoxicillin is indicated in the treatment of infections caused by susceptible strains of the following microorganisms:

Infections of the genitourinary tract caused by microorganisms including Gonorrhoea, *E. Coli*, *P. mirabilis*, *enterococci*, *Shigella*, *S. typhosa*, *N. gonorrhoea*, *Salmonella* and other non penicillinase producing microorganisms.

Infections of the respiratory tract caused by microorganisms such as non-penicillinase producing H. influenzae, *staphylococci*, and *streptococci*, including *Streptococcus pneumoniae*.

Infections of the gastrointestinal tract caused by microorganisms such as *Shigella*, *S. typhosa*, *Salmonella*, *E.Coli*, *P. mirabilis* and *enterococci*. Meningitis N. meningitides.

Bacteriology studies to determine the causative organisms and their sensitivity to Amoxicillin should be performed. Therapy may be instituted prior to the results of susceptibility testing.

Amoxicillin is also used in the treatment of infections of the respiratory tract such as pneumonia and bronchitis and is especially effective where *Haemophilus influenzae* is the causative organism although the incidence of resistant strains is increasing.

CONTRAINDICATIONS: A history of allergic reaction to any of the penicillin is a contraindication. The use of this drug is contraindicated in individuals with a history of previous hypersensitivity reaction to any of the penicillins. Amoxicillin is also contraindicated in infections caused by penicillinase producing organisms.

DRUG INTERACTIONS: Probenecid decreases the renal tubular secretion of Amoxicillin, concurrent use of Amoxicillin and Probenecid may result in increased and prolonged blood levels of amoxicillin. Chloramphenicol, macrolides, sulfonamides and tetracyclines may interfere with the bactericidal effects of amoxicillin. This has been demonstrated invitro, however, the clinical significance of this interaction is not well documented.

Pseudomembranous colitis has been reported with nearly all-antibacterial agents, including amoxicillin, any may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhoea subsequent to the administration of antibacterial agents.

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Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by clostridium difficile is a primary cause of 'antibiotic-associated colitis'. After the diagnosis of pseudomembranous colitis has been established, appropriate therapeutic measure should be initiated. Mild cases of pseudomembranous colitis usually respond to drug discontinuation alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment and with antibacterial drug clinically effective against Clostridium difficile colitis.

WARNINGS: Serious and occasionally fatal hypersensitivity reactions have been reported in patients on parenteral penicillin therapy. These reactions may occur with oral penicillin particularly in individuals with a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before therapy with any penicillin careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens. If an allergic reaction occurs, appropriate therapy should be instituted and discontinuation of amoxicillin therapy considered. Serious anaphylactoid reactions require immediate emergency treatment with Epinephrine, oxygen, intravenous steroids and air way management including intubation should also be administered as indicated.

USAGE IN PREGNANCY: Safety for use in pregnancy has not been established.

PRECAUTIONS: As with any potent drug periodic assessment of renal, hepatic and hematopoietic function should be made during prolonged therapy. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy.

If superinfections occur (usually involving *Entero-bacter*, *pseudomonas* or *Candida*), the drug should be discontinued and/or appropriate therapy instituted.

ADVERSE REACTIONS: As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. They 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 following adverse reactions have been reported as associated with the use of penicillin.

Gastrointestinal : Nausea, vomiting and diarrhoea.

Hypersensitivity: Erythematous maculopapular rashes and urticaria have been reported.

Note: Urticaria, other skin rashes and serum sickness-like reactions, may be controlled with antihistamines and, if necessary systemic corticosteroids. Whenever such reactions occur Amoxicillin should be discontinued unless, in the opinion of the physician, the condition being treated is life-threatening and amenable only to Amoxicillin therapy.

Liver: A moderate use in serum glutamic oxaloacetic transaminases (SGOT) has been noted but the significance of this finding is unknown.

Central Nervous System: Reversible hypersensitivity, agitation, anxiety, insomnia, confusion, behavioral changes and/or dizziness have reported rarely.

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

DOSAGE AND ADMINISTRATION: Amoxicillin capsules, tablets & oral suspension may be given without regards to meals. The usual dosage regimen of amoxicillin is 250-500mg three times a day. For children half of the adult dose may be used. Some infections may be treated with special dosage regimens given below:

- a) Respiratory tract infections - 3g twice a day
- b) Acute urinary tract infections - 3g repeated once 12 hours later.
- c) Gonorrhoea - 3g single dose.
- d) Dental Abscess - 3g repeated once 8 hours later.
- e) Prophylaxis of endocarditis - Single 3 g dose one hour before dental procedure from which bacteraemia may arise. Repeated 6 hours later if necessary.

OVERDOSES/CONTRAINDICATIONS: In case of overdose, discontinue medication, treat symptomatically and institute supportive measures as required. In patients with renal function impairment, Amoxicillin class antibiotics can be removed by haemodialysis but not by peritoneal dialysis.

STORAGE CONDITIONS: Store in a cool dry place. Protect from light. Temperature not exceeding 25°C.

Keep all medicines out of sight and reach of children.

PRESENTATION:

Dosage form	Strength	Pack
SPAMOX CAPSULES	250mg / 500mg	Blister/Strip Pack of 10 x 10 Capsules Blister/Strip Pack of 100 x 10 Capsules Jar pack of 100/250/500/1000 Capsules
SPAMOX TABLETS	125mg & 250mg & 500mg	Blister / Strips pack of 10 x 10 Tablets Blister / Strips pack of 100 x 10 Tablets Jar pack of 100/250/500/1000 Tablets
SPAMOX ORAL SUSPENSION	125mg / 5ml & 250mg / 5ml	Bottles of 60ml & 100ml



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SPARSH BIO-TECH PVT. LTD.
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