

## AMOXITID

### Capsules & Suspension

#### Composition

##### Amoxitid 250 Capsules

Each capsule contains Amoxicillin (as trihydrate) 250 mg.

##### Amoxitid 500 Capsules

Each capsule contains Amoxicillin (as trihydrate) 500 mg.

##### Amoxitid 750 Capsules

Each capsule contains Amoxicillin (as trihydrate) 750 mg.

##### Amoxitid 125 Suspension

Each teaspoonful (5 ml) contains Amoxicillin (as trihydrate) 125 mg.

##### Amoxitid 250 Suspension

Each teaspoonful (5 ml) contains Amoxicillin (as trihydrate) 250 mg.

##### Amoxitid 400 Suspension

Each teaspoonful (5 ml) contains Amoxicillin (as trihydrate) 400 mg.

#### Action

Amoxycillin is a semisynthetic aminopenicillin of the beta-lactam group of antibiotics. It has a broad spectrum of antibacterial activity against many Gram-positive and Gram-negative microorganisms, acting through the inhibition of biosynthesis of cell wall mucopeptide. Amoxycillin is, however, susceptible to degradation by beta-lactamases and therefore the spectrum of activity does not include organisms that produce these enzymes including resistant staphylococci, and all strains of *Pseudomonas*, *Klebsiella*, and *Enterobacter*.

Strains of the following organisms are generally sensitive to the bactericidal action of amoxycillin *in vitro*:

##### Gram-positive

*Streptococcus faecalis*  
*Streptococcus pneumoniae*  
*Streptococcus pyogenes*  
*Streptococcus viridans*  
*Staphylococcus aureus* (penicillin sensitive)  
*Clostridium* species  
*Corynebacterium* species  
*Bacillus anthracis*  
*Listeria monocytogenes*

##### Gram-negative

*Haemophilus influenzae*  
*Escherichia coli*  
*Proteus mirabilis*  
*Salmonella* species  
*Shigella* species  
*Bordetella pertussis*  
*Brucella* species  
*Neisseria gonorrhoeae*  
*Neisseria meningitidis*  
*Pasteurella septica*  
*Helicobacter pylori*  
*Leptospira* spp  
*Fusobacterium* spp  
*Vibrio Cholerae*

##### Other

*Borrelia burgdorferi*

#### Pharmacokinetics

**Absorption:** Amoxycillin is rapidly absorbed from the gut to an extent of 72-93%. Absorption is independent of food intake.

**Distribution:** Peak blood levels are achieved 1-2 hours after administration. After 250 and 500 mg doses of amoxycillin, average peak serum concentrations of 5.2 mcg/ml and 8.3 mcg/ml respectively have been reported.

Amoxycillin is not highly protein bound; approx. 18% of total plasma drug content is bound to protein. Amoxycillin diffuses readily into most body tissues and fluids, with the exception of the brain and

spinal fluid. Inflammation generally increases the permeability of the meninges to penicillins and this may apply to amoxicillin.

*Excretion:* The major route of elimination for amoxicillin is via the kidney. Approximately 60-70% of amoxicillin is excreted unchanged in urine during the first 6 hours after administration of a standard dose. The elimination half-life is approximately 1 hour. Amoxicillin is also partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to 10-25% of the initial dose. Concurrent administration of probenecid delays amoxicillin excretion.

Small amounts of the drug are also excreted in feces and bile.

### **Indications**

- Infections caused by amoxicillin-susceptible organisms including upper respiratory tract infections, chest infections, urinary tract infections, skin and soft tissue infections, and gonorrhoea.
- Amoxicillin may be used for the prevention of bacteraemia associated with procedures such as dental extraction in patients at risk of developing bacterial endocarditis.

### **Contraindications**

- Known hypersensitivity to a penicillin-type drug.
- This drug should not be administered to babies born to mothers with a history of hypersensitivity to a penicillin type drug.

### **Warnings**

Serious and occasionally even fatal hypersensitivity reactions due to penicillin therapy have been reported. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients receiving oral penicillins. Such reactions are more likely to occur in individuals with a history of hypersensitivity to penicillins and/or a history of sensitivity to multiple allergens. There have also been reports of individuals with a history of penicillin hypersensitivity experiencing severe reactions when treated with cephalosporins.

Therefore before initiating therapy with this drug, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens, because of the risk of anaphylactoid reactions.

If an allergic reaction occurs, the drug should be discontinued and appropriate therapy instituted.

Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management including intubation, should also be administered as indicated.

This drug should not be used in patients suffering from mononucleosis, since these patients run a high risk of developing a skin rash.

### **Pregnancy**

#### *Category B*

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

### **Nursing Mothers**

Since penicillins are excreted in breast milk, administration of this drug to nursing mothers may lead to sensitization of their infants. Therefore, having taken into account the importance of the drug to the mother, either discontinue nursing or discontinue the drug.

### **Use in Infants**

Penicillins are excreted largely unchanged by the kidney. Because renal function is incompletely developed in infants, the rate of elimination of the drug tends to be slow. Penicillin-type drugs should therefore be administered with caution, particularly in neonates, and organ system function should be evaluated frequently.

### **Adverse Reactions**

As with other penicillins, it may be expected that untoward reactions will be essentially limited to sensitivity phenomena. These 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.

In common with other  $\beta$ -lactam antibiotics, angioedema and anaphylaxis may occur. The following adverse reactions have been reported as being associated with the use of penicillins.

#### **Hypersensitivity**

Anaphylaxis is the most serious potential adverse reaction to a penicillin drug. It is usually associated with the administration of parenteral rather than oral dosage forms. Serious anaphylactoid reactions require immediate emergency treatment with adrenaline. Oxygen, intravenous steroids and airway management including intubation, should also be administered as indicated.

Erythematous maculopapular rashes, urticaria, and occasional cases of exfoliative dermatitis, erythema multiforme and Stevens-Johnson syndrome have been reported. Laryngeal edema and serum sickness-like reactions including chills, fever, edema and arthralgia have also been reported. Such reactions may be controlled with antihistamines and, if necessary, systemic corticosteroids. Whenever such reactions occur, the drug should be discontinued unless, in the opinion of the physician, the condition being treated is life threatening and amenable only to penicillin therapy.

#### **Gastrointestinal**

Clostridiosis, stomatitis, black "hairy" tongue, nausea, vomiting, enterocolitis, pseudomembranous colitis and diarrhea have been observed.

#### **Hepatic**

A moderate rise in serum glutamic oxaloacetic transaminase (SGOT) and/or serum glutamic pyruvic transaminase (SGPT) has been noted, particularly in infants, but the significance of this finding is unknown. Rare cases of transient hepatitis and cholestatic jaundice have been reported.

#### **Haematological**

Haematological reactions including haemolytic anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, Leukopenia, and agranulocytosis have been observed. These are believed to be hypersensitivity phenomena and are usually reversible upon discontinuation of therapy.

#### **Central Nervous System**

Rare cases of reversible hyperactivity, agitation, anxiety, insomnia, confusion, behavioural changes, and/or dizziness have been reported.

### **Precautions**

In the treatment of group A,  $\beta$ -haemolytic streptococcal infections, therapy with this drug should be continued for at least 10 days to help prevent the occurrence of acute rheumatic fever or glomerulonephritis. Following completion of treatment, cultures should be taken to determine whether streptococci have been eradicated.

As with any potent drug, periodic assessment of renal, hepatic and hematopoietic functions should be made during prolonged therapy.

The possibility of super infection with mycotic or bacterial pathogens should be kept in mind during therapy. If super infection occurs, appropriate therapy should be instituted.

## **Drug Interactions**

*Penicillins/ Chloramphenicol/ Erythromycin/ Tetracyclines/ Sulfonamide*

Since bacteriostatic drugs may interfere with the bactericidal effect of penicillins in the treatment of meningitis or other conditions where a rapid bactericidal effect is necessary, it is best to avoid concurrent therapy.

*Penicillins/ Probenecid*

Probenecid may decrease renal tubular secretion of penicillin-type drugs, resulting in increased blood levels.

## **Diagnostic Interference**

Treatment with penicillins may result in false positive reactions when testing for the presence of glucose in urine using Clinitest, Benedict's Solution or Fehling's Solution. Tests based on enzymatic glucose oxidase reactions such as Clinistix or Test-Tape is not affected.

A transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone, and estradiol has been noted following administration to pregnant women.

## **Dosage and Administration**

Amoxitid is not affected by food and may therefore be administered without regard to meals.

With the exception of gonorrhoea, treatment with Amoxitid should be continued for a minimum of 48-72 hours beyond the time at which the patient becomes asymptomatic or evidence of bacterial eradication has been obtained.

In the treatment of group A,  $\beta$ -haemolytic streptococcal infections, therapy with this drug should be continued for at least 10 days to help prevent the occurrence of acute rheumatic fever or glomerulonephritis.

## **Upper Respiratory Tract and Chest Infections**

*Adults and Children over 10 Years of Age*

The recommended dosage is 250-500 mg 3 times daily, every 8 hours.

*Infants and Children under 10 Years of Age*

In infants under 2 years of age, the dosage is 62.5 mg 3 times daily, every 8 hours.

In children 2-10 years of age, the dosage is 125 mg 3 times daily, every 8 hours. For more severe infections, the dosage may be increased to 250 mg 3 times daily.

The recommended dosage according to body weight is 20 mg/kg per day in divided doses every 8 hours. For more severe infections, the dosage may be increased to 40 mg/kg body weight per day every 8 hours.

## **Skin and Soft-tissue Infections**

Treat as for upper respiratory tract and chest infections.

## **Uncomplicated Lower Urinary Tract Infections**

*Adults*

A single dose of 3 grams may be administered.

*Children*

A single dose of 100 mg/kg body weight may be administered.

## **Gonorrhoea**

A single dose of 3 grams may be administered.

**Prophylaxis of Bacterial Endocarditis (in dental procedures)***Adults and Children over 10 Years of Age*

A single dose of 3 grams about 1 hour prior to the procedure, to prevent bacteraemia.

*Children under 10 Years of Age*

Half the adult dose.

**Over Dosage**

Over Dosage of penicillin, drugs may cause neuromuscular hyperirritability or convulsive seizures.

Discontinue medication, treat symptomatically, and institute supportive measures as required. In patients with renal function impairment, the antibiotic may be removed from the circulation by haemodialysis, not by peritoneal dialysis.

**Pharmaceutical Precautions**

No refrigeration of Amoxitid suspension is required prior to reconstitution. However, following reconstitution, it is preferable to keep the suspension in a refrigerator. Any unused portion of the suspension must be discarded after 10 days.

**Presentation****Amoxitid 250 Capsules**

Box of 16 capsules.

**Amoxitid 500 Capsules**

Box of 16 capsules.

**Amoxitid 750 Capsules**

Box of 12 capsules.

**Amoxitid 125 Suspension**

Powder for the preparation of 60 ml, 100 suspension.

**Amoxitid 250 Suspension**

Powder for the preparation of 60 ml, 100 suspension.

**Amoxitid 400 Suspension**

Powder for the preparation of 70 ml suspension.