

# Amoxguard

Amoxicillin BP

125 mg/5 ml PFS

COMPOSITION

AMOXGUARD PFS : When reconstituted each 5 ml suspension contains Amoxicillin Trihydrate BP equivalent to 125 mg Amoxicillin BP

PHARMACOLOGY

AMOXGUARD (Amoxicillin BP) is a semisynthetic broad-spectrum antibiotic with bactericidal activity against many gram-positive and gram-negative microorganisms. Amoxicillin is more rapidly & more completely absorbed and producing higher plasma and tissue concentration than ampicillin. Peak plasma concentration of Amoxicillin is achieved within 1 to 2 hours.

INDICATION

AMOXGUARD (Amoxicillin BP) is indicated in the treatment of following infections:

- **Upper respiratory tract/ENT infections** : Pharyngitis, laryngitis, tonsillitis, sinusitis, otitis media
- **Lower respiratory tract infections** : Bronchitis, bronchiectasis, pneumonia, lung abscess
- **Gastrointestinal tract infections** : Typhoid, para-typhoid, cholecystitis, peritonitis
- **Genito-urinary tract infections** : Nephritis, pyelonephritis, cystitis, urethritis, bacteriuria, intra-abdominal sepsis, puerperal sepsis, septic abortion, gonorrhoea
- **Skin and soft tissue infections** : Boils, carbuncles, cellulitis, furuncles, abscess prophylaxis of endocarditis, before and after dental surgery
- **H. pylori eradication** : In combination with PPI plus clarithromycin/Metronidazole
- **Other infections** : Meningitis, osteomyelitis, septicaemia

DOSAGE AND ADMINISTRATION

Dose should be individualized, depending on patient's conditions and response.

AMOXGUARD (Amoxicillin BP) capsules and oral suspension may be given without regards to meals.

Adults and Children >3 Months :

Infection	Severity	Adult Dose	Dose for Children >3 Months
Ear/Nose/Throat Skin and soft tissue Genitourinary Tract	Mild/ Moderate	500 mg 12 hrly or 250 mg 8 hrly	25 mg/kg/day in divided doses 12 hrly or 20 mg/kg/day in divided doses 8 hrly
	Severe	875 mg 12 hrly or 500 mg 8 hrly	45 mg/kg/day in divided doses 12 hrly or 40 mg/kg/day in divided doses 8 hrly
Lower Respiratory Tract	Mild/ Moderate	875 mg 12 hrly or 500 mg 8 hrly	45 mg/kg/day in divided doses 12 hrly or 40 mg/kg/day in divided doses 8 hrly
Gonorrhea, Acute uncomplicated ano-genital and urethral		3 g Amoxicillin + 1 g probenecid as single dose	Children (>2 years) : 50 mg/kg Amoxicillin +25 mg/kg probenecid as a single dose
Anthrax (treatment and post- exposure prophylaxis)		500 mg 8 hrly	Body-weight under 20 kg : 80 mg/kg/day 8 hrly; Body-weight over 20 kg : Adults dose.

Neonates and Infants (12 weeks or 3 Months) : Due to incomplete renal function, the recommended upper dose of Amoxicillin is 30 mg/kg/day in divided doses 12 hrly.

Special dosage	Short-course therapy
Otitis Media : Adults :1 g 8 hrly. Children : 40 mg/kg/day 8 hrly.  H. pylori eradication : Amoxicillin 1 g twice daily/Amoxicillin 500 mg thrice daily + Clarithromycin 500 mg twice daily/ Metronidazole 400 mg twice daily + Proton pump inhibitor, Esomeprazole 20 mg/ Omeprazole 20 mg twice daily for 7-14 days.  Chlamydi atrachomatis in pregnancy : 500 mg 3 times a day for 7 days.	For the prophylaxis of endocarditis in patients at risk during dental procedure : Amoxicillin 2 or 3 g is given about one hour before dental procedure.  Dental abscesses : A single dose of 3 g and repeated once after 8 hours.  Uncomplicated acute UTIs : A single dose of 3 g and repeated once after 10-12 hours.  In severe or recurrent RTIs : 3 g 12 hrly.  Otitis Media (3-10 years) : 750 mg 12 hrly for 2 days

Hepatic Impairment : No dose adjustment is necessary.

Renal Impairment : Dosage of Amoxicillin should be reduced according to creatinine clearance (CC) :

\* CC 10-30 ml/min: 250-500 mg 12 hrly. \* CC less than 10 ml/min: 250-500 mg 24 hrly.

\* Haemodialysis patients: 250-500 mg 24 hrly.

CONTRAINDICATION

AMOXGUARD is contraindicated in known hypersensitivity to Amoxicillin or penicillins.

PRECAUTION

Amoxicillin should be used with caution in I. history of allergy II. renal impairment III. history of colitis IV. erythematous rashes common in glandular fever V. cytomegalovirus infection VI. acute or chronic lymphocytic leukemia. like other antibiotics, pseudomembranous colitis has been reported.

IN PREGNANCY AND LACTATION

Pregnancy : Pregnancy category B. Not known to be harmful nevertheless should be used during pregnancy only if clearly needed.

Lactation : Penicillins is excreted in breast-milk. So, it should be used with caution in nursing mothers and only if the expected benefit to the mother is greater than the possible risk to the nursing infant.

SIDE EFFECT

Adverse reactions are usually mild and transient. The main adverse reactions are nausea, vomiting diarrhoea, urticaria, skin rashes, anaemia, hemorrhagic colitis, hay fever, asthma, hepatic dysfunction, crystalluria, insomnia, confusion, dizziness.

DRUG INTERACTION

Probenecid : excretion of Amoxicillin is reduced, therefore plasma concentration is increased. Allupurinol : increased risk of rash. Cytotoxic (Methotrexate) : increased risk of Methotrexate toxicity.

DIRECTION FOR RECONSTITUTION OF AMOXGUARD PFS

Shake the bottle until all powder flows freely. Add 60 ml (6 Cup) boiled & cool water for AMOXGUARD PFS and shake well to suspend powder. For better mixing add total water in two portion and shake well each time.

Note : After reconstitution keep the bottle tightly closed and shake the bottle well before each use. Reconstituted suspension must be used within 7 days if kept at room temperature or within 10 days when stored in a refrigerator.

STORAGE

Store below 30° C in a cool, dry place and away from light. Keep all medicine out of the reach of children.

HOW SUPPLIED

AMOXGUARD PFS: Each Bottle containing powder to make 100 ml suspension when reconstituted.



Manufactured by:

**GUARDIAN**  
**Healthcare Ltd.**  
Amtola, Zirabo, Ashulia  
Dhaka, Bangladesh.