

Composition

Apoxy-500 Capsule: Each capsule contains Amoxicillin 500 mg (as Amoxicillin Trihydrate BP)

Apoxy PFS 100 ml: After reconstitution each 5 ml suspension contains Amoxicillin 125 mg (as Amoxicillin Trihydrate BP)

Pharmacology

Amoxicillin is a semisynthetic antibiotic with a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms. Amoxicillin kills bacteria by interfering with the synthesis of the bacterial cell wall. Amoxicillin is stable at gastric pH. It is completely absorbed in the upper gastrointestinal tract. Absorption is independent of meals.

Indication

Apoxy is indicated in the treatment of infection due to susceptible strains of the designated microorganisms in the condition listed below: Infections of the ear, nose and throat due to *Streptococcus spp.* (α and β-hemolytic strains only), *S. pneumoniae*, *Staphylococcus spp.*, or *H. influenzae*. Infections of the genitourinary tract due to *E. coli*, *P. mirabilis*, or *E. faecalis*. Infections of the skin and skin structure due to *Streptococcus spp.* (α and β-hemolytic strains only), *Staphylococcus spp.*, or *E. coli*. Infections of the lower respiratory tract due to *Streptococcus spp.* (α and β-hemolytic strains only), *S. pneumoniae*, *Staphylococcus spp.*, or *H. influenzae*. Gonorrhoea, acute uncomplicated (ano-genital and urethral infections) due to *N. gonorrhoeae* (males and females). *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence in combination with Clarithromycin plus Lansoprazole as triple therapy.

Dosage & Administration

Infection	Severity	Usual Dose for Adult	Usual Dose for Children
Ear / Nose / Throat	Mild/ Moderate	500 mg every 12 hours or 250 mg every 8 hours	25 mg / kg / day in divided doses every 12 hours or 20 mg / kg / day in divided doses every 8 hours
	Severe	875 mg every 12 hours or 500 mg every 8 hours	45 mg / kg / day in divided doses every 12 hours or 40 mg / kg / day in divided doses every 8 hours
Lower Respiratory Tract	Mild/ Moderate or Severe	875 mg every 12 hours or 500 mg every 8 hours	45 mg / kg / day in divided doses every 12 hours or 40 mg / kg / day in divided doses every 8 hours
Skin / Skin Structure	Mild/ Moderate	500 mg every 12 hours or 250 mg every 8 hours	25 mg / kg / day in divided doses every 12 hours or 20 mg / kg / day in divided doses every 8 hours
	Severe	875 mg every 12 hours or 500 mg every 8 hours	45 mg/ kg/ day in divided doses every 12 hours or 40 mg/ kg/ day in divided doses every 8 hours
Genitourinary Tract	Mild/ Moderate	500 mg every 12 hours or 250 mg every 8 hours	25 mg / kg / day in divided doses every 12 hours or 20 mg / kg / day in divided doses every 8 hours
	Severe	875 mg every 12 hours or 500 mg every 8 hours	45 mg/ kg/ day in divided doses every 12 hours or 40 mg/ kg/ day in divided doses every 8 hours
Gonorrhoea, Acute uncomplicated ano-genital, and urethral infections in males and females		3 gm as single oral dose	Prepubertal children 50 mg/kg Amoxicillin combined with 25 mg/kg Probenecid as a single dose Note: Since Probenecid is contraindicated in children under 2 years, do not use this regimen in these cases.

Contraindication

It is contra-indicated in patients hypersensitive to penicillins.

Precaution

In renal impairment the excretion of antibiotic will be delayed and depending on the degree of impairment it may be necessary to reduce the total daily dose. Caution should also be exercised in case of erythematous rashes, glandular fever, history of allergy etc.

Side Effects

Side effects are mild, rare and infrequent. As with other penicillins it may induce diarrhea, indigestion or skin rashes which usually stop during treatment and rarely calls for discontinuation of therapy.

Use in Pregnancy & Lactation

Because of its lack of teratogenicity, Amoxicillin can be used safely throughout pregnancy at the normal adult dose. The small amount of Amoxicillin secreted in maternal milk rarely causes problems in the infant. It can therefore be used safely during lactation in most cases.

Drug Interaction

Concurrent administration of probenecid delays the excretion of Amoxicillin.

Overdose

There is no data on overdose with Amoxicillin.

Preparation of Suspension

Apoxy Powder for Suspension: Shake the bottle well before adding water. Then add 14 tea spoonsful (70 ml) of boiled and cooled water to the bottle and shake well to make 100 ml suspension.

Storage

Apoxy-500 Capsule: Keep away from light & moisture and store below 30° C. Keep out of the reach of children.

Apoxy Powder for Suspension: Keep away from light & moisture and store below 25° C. Keep out of the reach of children.

The reconstituted suspension must be used within 7 days if kept at room temperature and within 10 days when stored in a refrigerator.

Packaging

Apoxy 500 Capsule: Each box contains 5 X 10's capsules in Blister Strips.

Apoxy PFS 100 ml: Each bottle contains dry powder to make 100 ml suspension.