

### COMPOSITION

**Moxacil**® 250 Capsule: Each capsule contains Amoxicillin 250 mg (as Amoxicillin Trihydrate BP).

**Moxacil**® 500 Capsule: Each capsule contains Amoxicillin 500 mg (as Amoxicillin Trihydrate BP).

**Moxacil®** Powder for Suspension: After reconstitution each 5 ml suspension contains Amoxicillin 125 mg (as Amoxicillin Trihydrate BP).

**Moxacil®** Paediatric Drops: After reconstitution each 1.25 ml 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

**Moxacil**<sup>®</sup> is indicated in the treatment of infections due to susceptible strains of the designated microorganisms in the condition listed below:

Infections of the ear, nose, and throat due to *streptococcus* spp. ( $\alpha$  and  $\beta$ -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. ( $\alpha$  and  $\beta$ -hemolytic strains only), *Staphylococcus* spp., or *E. Coli*.

Infections of the lower respiratory tract due to *Streptococcus* spp. ( $\alpha$  and  $\beta$ -hemolytic strains only), *S. pneumoniae, Staphylococcus* spp., or *H. influenzae*. Gonorrhea, acute uncomplicated (ano-genital and urethral infections) due to *N. gonorrhoeae* (male and females). *H. pylori* eradication to reduce the risk of duodenal ulcer recurrence in combination with Clarithromycin plus Lansoprazol as triple therapy.

**Moxacil®** may also be used as prophylactic cover for patients at risk of vdeveloping endocarditis when undergoing dental surgery.

### 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.

## ADVERSE EFFECT

Adverse effects are mild, rare and infrequent. As with other penicillins it may induce diarrhoea, 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 instances.

### **DRUG INTERACTION**

Concurrent administration of probenecid delays the excretion of Amoxicillin.

### **DOSAGE AND ADMINISTRATION**

Infection	Severity	Usual Adult Dose	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 20mg/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 20mg/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 20mg/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
Gonorrhea, Acute, uncomplicated ano-genital, and urethral infections in males and females		3 g 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.

# **RECONSTITUTION & ADMINISTRATION**

**Moxacil**® Powder for Suspension:

Shake the bottle well before adding water. Then add 12 tea spoonful (60 ml) of boiled and cooled water to the bottle and shake well to make 100 ml suspension.

### **STORAGE**

Store in a cool and dry place protected from light and moisture. The reconstituted suspension must be used within 7 days if kept at room temperature and within 10 days when stored in a refrigerator.

# **HOW SUPPLIED**

Moxacil® 250 Capsule: Each box contains 100 capsules in blister pack.

Moxacil® 500 Capsule: Each box contains 100 capsules in blister pack.

**Moxacil**® Powder for Suspension: Each bottle contains dry powder to make 100 ml suspension

**Moxacil®** Paediatric Drops: Each bottle contains dry powder to make 15 ml drops.

Manufactured by



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