# MOXACIL®
# Amoxicillin BP
# Capsules / Suspension

**Composition:**
Each capsule contains Amoxicillin (as Trihydrate) BP 250mg or 500mg.
Each 5ml of the reconstituted suspension contains Amoxicillin (as Trihydrate) BP 125mg
Each 5 ml of the reconstituted suspension of Moxacil DS contains Amoxicillin (as trihydrate) BP 250mg
**List of excipients:**
**Capsule:** Magnesium stearate, microcrystalline cellulose and Sodium lauryl sulphate.
**Dry powder:** Orange Flavor, Sodium Benzoate, Sodium Citrate, Disodium Edetate, Egg Yellow Colour and Sucrose.
**Pharmacology:**
Amoxicillin is amino penicillin which exerts its antibacterial action on growing and dividing bacteria by inhibiting bacterial cell-wall synthesis, although the mechanisms involved are still not precisely understood. Bacterial cell walls are held rigid and protected against osmotic rupture by peptidoglycan. Benzylpenicillin inhibits the final cross-linking stage of peptidoglycan production by binding to and inactivating transpeptidases, penicillin-binding proteins on the inner surface of the bacterial cell membrane. However, it is now realised that other earlier stages in cell-wall synthesis can also be inhibited. Other mechanisms involved include bacterial lysis by the inactivation of endogenous inhibitors of bacterial autolysins.
**Spectrum of activity:** Amoxicillin resembles benzylpenicillin in its action against Gram-positive organisms, including Streptococcus pneumoniae and other streptococci. Listeria monocytogenes is highly sensitive. The Gram-negative cocci Moraxella catarrhalis (Branhamella catarrhalis), Neisseria gonorrhoeae, and N. meningitidis are sensitive. Amoxicillin is more active than benzylpenicillin against some Gram-negative bacilli, including Haemophilus influenzae and Enterobacteriaceae such as Escherichia coli, Proteus mirabilis, Salmonella and Shigella spp.
It is inactive against Pseudomonas aeruginosa. Amoxicillin also has activity similar to benzylpenicillin against other organisms including many anaerobes and Actinomyces spp.
**Pharmacokinetics:**
Amoxicillin is more rapidly and more completely absorbed than amoxicillin when administered orally. Peak plasma-amoxicillin concentrations of about 5 micrograms/mL are achieved in 1 to 2 hours after a dose of 250 mg, with detectable amounts present for up to 8 hours.
Doubling the dose can double the concentration. The presence of food in the stomach does not appear to diminish the total amount absorbed. Concentrations of amoxicillin after intramuscular injection are similar to those achieved with oral administration.
About 20% is bound to plasma proteins and plasma half-lives of 1 to 1.5 hours have been reported. The half-life may be prolonged in neonates, the elderly, and patients with renal impairment; in severe renal impairment the half-life may be 7 to 20 hours. Amoxicillin is widely distributed at varying concentrations in body tissues and fluids. It crosses the placenta; small amounts are distributed into breast milk. Little amoxicillin passes into the cerebral spinal fluid unless the meninges are inflamed. Amoxicillin is metabolized to a limited extent to penicilloic acid which is excreted in the urine. About 60% of an oral dose of amoxicillin is excreted unchanged in the urine in 6 hours by glomerular filtration and tubular secretion. Urinary concentrations above 300 micrograms/mL have been reported after a dose of 250 mg. Probenecid reduces renal excretion.
Amoxicillin is removed by hemodialysis. High concentrations have been reported in bile; some may be excreted in the faeces.
**Precautions:**
Patients known to be hypersensitive to penicillins should be given an antibacterial agent of another class. However, sensitized patients may also react to the cephalosporins and other beta lactams. Desensitization may be attempted if treatment with a penicillin is considered essential.
Care is necessary if very high doses of penicillins are given, especially if renal function is poor, because of the risk of Neurotoxicity.
**Pregnancy and Lactation:**
Use in pregnancy: Animal studies with Amoxicillin have shown no teratogenic effects. The product has been in extensive clinical use and its suitability in human pregnancy has been well documented in clinical studies. When antibiotic therapy is required during pregnancy, Amoxicillin may be considered appropriate when the potential benefits outweigh the potential risks associated with treatment.
Use in lactation: Amoxicillin may be given during lactation. With the exception of the risk of sensitization associated with the excretion of trace quantities of amoxicillin in breast milk, there are no known detrimental effects for the breast-fed infant.
Adverse reactions:
Skin rashes are among the most common adverse effects and are generally either urticarial or maculopapular. Gastrointestinal adverse effects, particularly diarrhoea and nausea and vomiting, occur quite frequently, usually following oral use. Pseudomembranous colitis has also been reported.
**Administration and Dosage:**
The usual oral dose is 250 to 500 mg every 8 hours.
Children up to 10 years of age may be given 125 to 250 mg every 8 hours;
For those under 40 kg, a dose of 20 to 40 mg/kg daily in divided doses every 8 hours
May be used; in infants less than 3 months old, the maximum dose should be 30 mg/kg daily in divided doses every 12 hours.
Higher oral doses of amoxicillin, either as a single dose or in short courses are used in some conditions. For example, a dose of 3 g repeated once after 8 hours may be used for dental abscesses.
A 3-g dose may be given for uncomplicated acute urinary-tract infections, and repeated once after 10 to 12 hours.
A high-dose regimen of 3 g twice daily may be used in patients with severe or recurrent infections of the respiratory tract.
Amoxicillin can also been given as a single dose of 3 g, with probenecid 1 g, in the treatment of uncomplicated gonorrhoea in areas where gonococci remain sensitive. For the prophylaxis of endocarditis in patients at risk, amoxicillin 2 or 3g is given about 1 hour before dental procedures. For the eradication of H. pylori, amoxicillin is given with either Metronidazole or clarithromycin and a proton pump inhibitor or ranitidine bismuth citrate; usual doses of amoxicillin are 0.75 or 1 g twice daily or 500 mg three times daily.
**Overdosage and treatment:**
Gastrointestinal effects such as nausea, vomiting and diarrhoea may be evident and should be treated symptomatically with attention to the water/electrolyte balance.
Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.
Amoxicillin may be removed from the circulation by haemodialysis.
**Presentation:**
Capsules: 10 x 10 capsule blisters in unit carton pack. Or HDPE Jars containing 1000 capsules of 250mg and 500 capsules of 500mg.
Oral suspension: dry powder for reconstitution in 60ml and 100ml bottles.
**Shelf life:**
Capsules: 3 years from the date of manufacture.
Dry powder for suspension: 3 years from the date of manufacture, to be used within 7 days once reconstituted.
**Distribution Category:**
POM
**Storage:**
Store in a cool dry place, below 30°C, protected from direct sunlight
Dry powder for suspension: Once reconstituted, store the bottle tightly closed in a cool dry place, below 30°C, preferably in a refrigerator.
Do not freeze.
Keep all medicines out of reach of children.
**Manufactured in Kenya by:**

**DAWA Limited, Plot No. 7879/8, Baba Dogo Road, Ruaraka**
**P. O. Box 16633 – 00620, Nairobi, Kenya.**

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