

**Composition : Demoxiclave-375** : Each film coated tablet contains amoxicillin 250mg (as Amoxicillin Trihydrate USP) with 125mg clavulanic acid as potassium clavulanate USP.

**Demoxiclave-625** : Each film coated tablet contains amoxicillin 500mg (as Amoxicillin Trihydrate USP) with 125mg clavulanic acid as potassium clavulanate USP.

**Demoxiclave-1 gm** : Each film coated tablet contains amoxicillin 875mg (as Amoxicillin Trihydrate USP) with 125mg clavulanic acid as potassium clavulanate USP.

**Demoxiclave suspension** : Each 5ml reconstituted suspension contains amoxicillin 125mg (as Amoxicillin Trihydrate USP) and clavulanic acid 31.25mg as potassium clavulanate USP.

**Description** : Demoxiclave is the brand name of co-amoxiclav which is an antibacterial combination consisting of the antibiotic amoxicillin and the b-lactamase inhibitor clavulanic acid. Amoxicillin has a broad spectrum of bactericidal activity against many gram-positive and gram-negative microorganisms but it is susceptible to degradation by b-lactamase and therefore the spectrum of activity does not include microorganisms which produce these enzymes. Clavulanic acid possesses the ability to inactivate a wide range of b-lactamase enzymes commonly found in microorganisms resistant to penicillins and cephalosporins. Thus the formulation of amoxicillin with clavulanic acid together in Demoxiclave protects amoxicillin from degradation by b-lactamase enzymes and effectively extends the antibiotic spectrum against a wide range of microorganisms.

**Indication** : Demoxiclave is indicated for short-term treatment of bacterial infections at the following sites :

- \* Upper respiratory tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media.
- \* Lower respiratory tract infections e.g. acute and chronic bronchitis, lobar and bronchopneumonia.
- \* Genito-urinary tract infections e.g. cystitis, urethritis, pyelonephritis.
- \* Skin and soft tissue infections
- \* Bone and joint infections e.g. osteomyelitis.
- \* Other infections e.g. septic abortion, puerperal sepsis, intra-abdominal sepsis, etc.

**Dosage & administration :**

**Adults** : 1 Demoxiclave-625 tablet every 12 hours or 1 Demoxiclave-375 tablet every 8 hours. For more severe infections and infections of the respiratory tract 1 Demoxiclave-625 tablet every 8 hours or 1 Demoxiclave-1 gm tablet every 12 hours.

Demoxiclave is administered at the start of a meal.

Children over 6 to 12 years : 2 teaspoonfuls of Demoxiclave oral suspension every 8 hours.

Children over 1 to 6 years : 1 teaspoonful of Demoxiclave oral suspension every 8 hours.

**Demoxiclave**

Tablet & Suspension



**DRUG  
INTERNATIONAL  
LTD.**

Children below 1 year : 25 mg/kg/day in divided doses every 8 hours.

Treatment should not be extended beyond 14 days without review. Or, as directed by the registered physician.

**Contra indications :**

- \* Penicillin hypersensitivity. Attention should also be given to possible cross sensitivity with other b-lactam antibiotics e.g. cephalosporins.
- \* A previous history of co-amoxiclav or penicillin associated cholestatic jaundice.

Use in pregnancy and lactation : Pregnancy Category B. There are no adequate and well controlled studies of use of amoxicillin in pregnant women. Amoxicillin may be administered to pregnant women only if clearly needed. Amoxicillin is excreted in human milk; consideration should be given discontinuing nursing temporarily during treatment with cefuroxime.

**Side effects** : Side effects as with amoxicillin are uncommon and mainly of a mild and transitory nature. Diarrhoea, pseudomembranous colitis, indigestion, nausea, vomiting and candidiasis have been reported. If gastrointestinal side effects occur with oral therapy, they may be reduced by taking Demoxiclave at the start of meals. Hepatitis and cholestatic jaundice have been reported rarely but are usually reversible. Urticarial and erythematous rashes sometimes occur. Rarely erythema multiforme, Stevens-Johnson Syndrome and exfoliative dermatitis have been reported. In common with other b-lactam antibiotics, angioedema and anaphylaxis have been reported.

**Precautions** : Demoxiclave should be used with care in patients on anticoagulation therapy or with severe hepatic dysfunction. In patients with moderate or severe renal impairment, dose should be adjusted.

Pharmaceutical precaution : After reconstitution, suspension should be kept in refrigerator (but not frozen) or within 2<sup>o</sup> - 8<sup>o</sup>C and used within 7 days.

**Packing :**

**Demoxiclave-375** : Each box contains 3 x 7's tablets in blister pack.

**Demoxiclave-625** : Each box contains 3 x 7's tablets in blister pack.

**Demoxiclave-1 gm** : Each box contains 1 x 7's tablets in blister pack.

**Demoxiclave suspension** : Bottle containing dry powder to make 100ml Demoxiclave oral suspension.