Demoxiclave Fort Suspension

DRUG INTERNATIONAL LTD.

Composition : Each 5ml reconstituted suspension contains Amoxicillin 400mg as Amoxicillin Trihydrate BP and Clavulanic acid 57.5mg as Clavulanate Postassium USP.

Pharmacology : Co-amoxiclav is an antibacterial combination consisting of the antibiotic Amoxicillin and the betalactamase inhibitor Clavulanic acid. Amoxicillin has a broad spectrum of bactericidal activity against many grampositive and gram-negative microorganisms but it is susceptible to degradation by beta-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 betalactamase enzymes commonly found in microorganisms resistant to penicillins and cephalosporins. Thus Clavulanic acid in Demoxiclave Forte protects Amoxicillin from degradation by beta-lactamase enzymes and effectively extends the antibacterial specttuma wide range of microorganisms.

Indications : Co-amoxiclav oral preparatim is indicated for the short-termtreatment of bacterial infections which is given below-upper respiratory-tract infections (including ENT) e.g. tonsillitis, sinusitis, otitis media., Lower respiratory-tract infections (e.g. acute & chronic bronchitis, bronchopneumonia). Skin and soft tissue infections (cellulitis, animal bites) Genito-urinary-tract infections e.g. (cystitis, urethritis pyelonephritis) bone & Joint infections e.g. osteomyelitis. other infections e.g. Septic abortion, purperal sepsis, intra-abdominal sepsis, etc.

Dosage and administration : The recommended daily dosage is : 25/3.6 mg/kg/day in mild to moderate infections (upper respiratory tract infections e.g recurrert tonsillitis, lower respiratory infections, and skin & soft tissue infections) 45/6.4 mg/kg/day for the treatment of more serious infections (upper respiratory tract infections, e.g. otitis media and sinusitis, lower respiratory infections eg. bronchopneumonia, and urinary tract infections).

Children over 2 years :

25/3.6 mg/kg/day : 2-6 years (13-21kg 2.5ml suspension b.i.d, 7-12 years (22-40kg) 5.0ml suspension b.i.d

45/6.4 mg/kg/day : 2-6 years (13-21kg)5.0ml suspension b.i.d, 7-12 years (22-40kg) 10.0ml suspension b.i.d

Children (2 months-2 years) :

Children under two years should be dosed according to body weight.

Weight (kg)	2	3	4	5	6	7	8	9	10	11	12	13	14	15
25/3.6 mg/kg/day (ml/b.i.d)	0.3	0.5	0.6	0.8	0.9	1.1	1.3	1.4	1.6	1.7	1.9	2.0	2.2	2.3
45/6.4 mg/kg/day (ml/b.i.d)	0.6	0.8	1.1	1.4	1.7	2.0	2.3	2.5	2.8	3.1	3.4	3.7	3.9	4.2

Infants with immature kidney function : Not recommended. Renal impairment : For children with a GFR of>30 ml/min. no adjustment in dosage is required. For children with a GFR of<30 ml/min, Demoxiclave Forte Suspension is not recommended. Hepatic impairment : Dose should be given with caution; monitor hepatic function at regular intervals. There is, as, yet insufficient evidence on which, to base a dosage recommendation. To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of coamoxiclav is optimised when taken at the start of a meal. Duration of therapy should be appropiate to the indication and should not exceed 14 days without review, Or, as directed by the registered physician.

Contraindication : Penicillin hypersensitivity. Attention should be paid to possible cross sensitivity with other beta-lactam antibiotics e.g. cephalosporins. A previous history of Co-amoxiclav or penicillin associated hepatic dysfunction.

Precautions : In patients with moderate to severe renal impairment co-amoxiclav is not recommended. Prolonged use may also be occasionally result overgrowth of non-susceptible organisms. Serious and occasionally fatal hypersensitivity (anaphylactoid) reactions have been reported in patient on penicillin therapy. Changes in liver function tests have been observed in some patient receiving coamoxiclav. The clinical significance of these changes is uncertain but co-amoxiclav should be used with caution in patients with evidence of hepatic dysfunction. Cholestatic jaundice which may be severe, but is usually reversible, has been reported rarely. Signs amd symptoms may not become apparent for several weeks after treatment has ceased. In patients with moderate or severe renal impairment Demoxiclave Forte is not recommended.

Side effects : Side effects, as with Amoxicillin are uncommon and mainly of a mild and transitory nature. Diarrhoea, indigestion, nausea, vomiting and candidiasis, have been reported. If gastrointestinal side effects occur with oral therapy, that may be reduced by taking Coamoxiclav 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 beta-lactam antibiotics angioedema and anaphylaxis have been reported.

Pregnancy and lactation : Pregnany 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.

Drug Interactions : Prolongation of bleeding time and prothrombin time have been reported in some patients receving Co-amoxiclav. Coamoxiclav should be used with care in patients or anticoagulation therapy. In common with other broad-spectrum antibiotics coamoxiclav may reduce the efficacy of oral contraceptives and patient should be warned accordingly. Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of co-amoxiclav and allopurinol.

Storage : Store below 30°C in a dry place.

Packing : Bottle containing powder for the preparation of 35ml suspension.