Moxaclav®

Amoxycillin+Clavulanic Acid

PRESENTATION:

Moxaclav ® 375 tablet : Each film coated tablet contains Amoxycillin BP 250 mg as trihydrate with Clavulanic acid USP 125 mg as potassium salt.

Moxaclav ® 625 Tablet : Each film coated tablet contains Amoxycillin BP 500 mg as trihydrate with Clavulanic acid USP 125 mg as potassium salt.

Moxaclav ® 1gm Tablet : Each film coated tablet contains Amoxycillin BP 875mg as trihydrate with Clavulanic acid USP 125 mg as potassium salt.

Moxaclav ® Suspension : Each 5 ml reconstituted suspension contains Amoxycillin BP 125 mg as trihydrate and Clavulanic acid USP 31.25 mg as potassium salt.

Moxaclav ® Forte Suspension: Each 5 ml reconstituted suspension contains Amoxycillin BP400 mg as trihydrate and Clavulanic acid USP 57.5 mg as potassium salt.

PHARMACOLOGY:

Pharmacodynamic properties: Co-amoxiclav is an antibacterial combination consisting of the antibiotic Amoxycillin and the Beta-lactamase inhibitor Clavulanic acid. Amoxycillin has a broad spectrum of bactericidal activity against many gram-positive &
gram-negative microorganisms but it is susceptible to degradation by beta-lactamases 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 beta-lactamase enzymes commonly found in microorganisms resistant to penicillins and cephalosporins. Thus Clavulanic acid in Moxaclav ® protects Amoxycillin from degradation by beta-lactamase enzymes and effectively extends the antibiotic spectrum to embrace a wide range of microorganisms.

Moxaclav ® is bactericidal to a wide range of organisms including:

Gram-positive:

Aerobes: Enterococcus faecalis, Enterococcus faecium, Streptococcus pyogenes, Streptococcus viridans, Staphylococcus aureus, Coagulase negative staphylococci (including Staphylococcus epidermidis), Corynebacterium species, Bacillus anthracis, Listeria monocytogenes.

Anaerobes: Clostridium species, Peptococcus species, Peptostreptococcus.

Gram negative:

Aerobes: Haemophilus influenzae, Moraxella catarrhalis, Escherichia coli, Proteus mirabilis, Proteus vulgaris, Klebsiella species, Salmonella species, Shigella species, Bordetella pertussis, Brucella species, Neisseria gonorrhoeae, Neisseria meningitidis, Vibrio cholerae, Pasteurella multocida.

Anaerobes: Bacteroides species including B fragilis.

Pharmacokinetic properties: The pharmacokinetics of the two components of Co-amoxiclav are closely matched. Peak serum levels of both occur about one hour after oral administration. Absorption of Co-amoxiclav is optimised at the start of a meal. Both clavulanate and amoxycillin have low levels of serum binding; about 70% remains free in the serum. Doubling the dosage of Co-amoxiclav approximately doubles the serum levels achieved.

INDICATION:

Moxaclav ® is indicated for short-term treatment of bacterial infections at the following sites:

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

DOSAGE & ADMINISTRATION:

Adults and children over 12 years:

The usual adult dose is one **Moxaclav®** 625mg tablet every 12 hours **or** one **Moxaclav®** 375 mg tablet every 8 hours.
For more severe infections and infections of the respiratory tract, the dose should be one **Moxaclav®**1gm tablet every 12 hours
or one **Moxaclav®** 625mg tablet every 8 hours.

Children:
For Moxaclav suspension:
Children 6-12 years : 2 teaspoonful every 8 hours.
Children 1-6 years : 1 teaspoonful every 8 hours.
Children below 1 year : 25 mg/kg/day in divided doses every 8 hours, for example a 7.5 kg child would require 2 ml **Moxaclav ®** suspension t.i.d.
Treatment should not be extended beyond 14 days without review.

For Moxaclav ® Forte suspension:
The usual recommended daily dosage is: 25/3.6 mg/kg/day in mild to moderate infections (upper respiratory tract infections e.g. recurrent tonsilitis, lower respiratory infections, and skin and 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 e.g. bronchopneumonia, and urinary tract infections)
The tables below give guidance for children.

Children of 2 to 12 years:
25/3.6 mg/kg/day 2-6 years (13-21 kg) 2.5 ml suspension b.i.d
7-12 years (22-40 kg) 5.0 ml suspension b.i.d
45/6.4 mg/kg/day 2-6 years (13-21 kg) 5.0 ml suspension b.i.d
7-12 years (22-40 kg) 10.0 ml suspension b.i.d

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

Weight in Kg.	2	3	4	5	6	7	8	9	10	11	12	13	14	15
25/3.6 mg/kg/day	0.3	0.5	0.6	0.8	0.9	1.1	1.3	1.4	1.6	1.4	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

Dosage in renal impairment:
The dose should be adjusted in case of patients with renal impairment.
Adults:
Mild impairment (Creatinine clearance > 30 ml/min): No change in dose.
Moderate impairment (Creatinine clearance 10- 30 ml/min): One Moxaclav ® tablet or one **Moxaclav ®** 625 mg tablet 12 hourly.
Severe impairment (Creatinine clearance < 10 ml/min): Not more than one Moxaclav ® tablet 12 hourly; **Moxaclav ®** 625 tablet is not recommended.
Children:
Similar reductions in dose should be made for children.

Dosage in hepatic impairment:
Dose with caution; monitor hepatic function at regular intervals.

Moxaclav® may be taken without regard to meals; however, absorption of Clavulanate potassium is enhanced when Amoxicillin/Clavulanic acid is administered at the start of a meal. To minimize the potential for gastrointestinal intolerance, Amoxicillin/Clavulanic acid should be taken at the start of the meal.

PRECAUTION & WARNING:

Co-amoxiclav should be used with care in patients on anti-coagulation therapy or with severe hepatic dysfunction. In patients with moderate or severe renal impairment, dosage should be adjusted. During the administration of high dose of **Moxaclav** ® adequate fluid intake and urinary output should be maintained to minimize the possibility of crystalluria.

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 cholestatic jaundice.

SIDE EFFECT:
Side effects, as with Amoxycillin, 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, that may be reduced by taking Co-amoxiclav 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.

DRUG INTERACTIONS:
Prolongation of bleeding time and prothrombin time have been reported in some patients receiving Co-amoxiclav. In common with other broad-spectrum antibiotics, Co-amoxiclav may reduce the efficacy of oral contraceptives and patient should be warned accordingly.
Concomitant use of allopurinol during treatment with amoxycillin can increase the likelihood of allergic skin reactions. There are no data on the concomitant use of Co-amoxiclav and allopurinol.

USE IN PREGNANCY & LACTATION:
Animal studies with orally and parenterally administered Co-amoxiclav have shown no teratogenic effect. The drug has been used orally in human pregnancy in a limited number of cases with no untoward effect; however use of Co-amoxiclav in pregnancy is not recommended unless considered essential by the physician. During lactation, trace quantities of amoxycillin can be detected in breast milk.

OVERDOSE:
Problems of overdose with Co-amoxiclav are unlikely to occur, if encountered gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Co-amoxiclav may be removed from the circulation by haemodialysis.

STORAGE:
Moxaclav ® should be stored at a temperature not exceeding 25^0C or below. Protect from light and moisture. Once reconstituted suspension should be kept in refrigerator (but not frozen) and should be used by 7 days.

HOW SUPPLIED:
Moxaclav ® **375 tablet :**Box containing 3 x 6 film coated tablets in Alu-Alu blister pack.
Moxaclav ® **625 tablet :**Box containing 3 x 6 film coated tablets in Alu-Alu blister pack.
Moxaclav ®**1gm tablet :** Box containing2 x 6 film coated tablets in Alu-Alu blister pack
Moxaclav ® **suspension:** HDPE Bottle containing dry powder to make 100 ml suspension and HDPE Bottle containing dry powder to make 60 ml suspension.
Moxaclav ® **Forte suspension :** HDPE Bottle containing dry powder to make 35 ml suspension.

Manufactured by:

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