Clamox®

Amoxicillin & Clavulanic Acid

Description: This combination of Amoxicillin & Clavulanic acid is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The ß lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other ß lactam antibiotics.

Pharmacokinetics: Amoxicillin and clavulanate potassium are well absorbed from the gastrointestinal tract after oral administration of amoxicillin/clavulanate potassium. The safety and efficacy of amoxicillin/clavulanate potassium have been established in clinical trials where amoxicillin/clavulanate potassium was taken without regard to meals.

Composition: Clamox® 375 Tablet: Each tablet contains Amoxicillin BP 250 mg & Clavulanic Acid USP 125 mg.
Clamox® 625 Tablet: Each tablet contains Amoxicillin BP 500 mg & Clavulanic Acid USP 125 mg.
Clamox® 1 gm Tablet: Each tablet contains Amoxicillin BP 875 mg & Clavulanic Acid USP 125 mg.
Clamox® 100 ml Powder for Suspension: After reconstitution each 5 ml contains Amoxicillin 125 mg as Amoxicillin trihydrate BP & Clavulanic Acid 31.25 mg as Clavulanate Potassium USP.
Clamox® DS 35 ml Powder for Suspension: After reconstitution each 5 ml contains Amoxicillin 400 mg as Amoxicillin trihydrate BP & Clavulanic Acid 57.5 mg as Clavulanate Potassium USP.
Clamox® 0.6 gm Injection: Each vial contains sterile mixture of Amoxicillin Sodium BP equivalent to Amoxicillin 500 mg and Clavulanate potassium USP equivalent to Clavulanic acid 100 mg.
Clamox® 1.2 gm Injection: Each vial contains sterile mixture of Amoxicillin Sodium BP equivalent to Amoxicillin 1 gm and Clavulanate potassium USP equivalent to Clavulanic acid 200 mg.

Indication: The combined oral preparations are indicated for short term treatment of bacterial infections at the following sites when amoxicillin resistant beta-lactamase producing strains are suspected as the cause. In other situations, amoxicillin alone should be considered.
Upper Respiratory Tract Infections (including ENT) in particular sinusitis, otitis media, recurrent tonsillitis.
Lower Respiratory Tract Infections in particular acute exacerbations of chronic bronchitis (especially if considered severe), bronchopneumonia.
Genito-urinary Tract and Abdominal Infections in particular cystitis (especially when recurrent or complicated - excluding prostatitis), septic abortion, pelvic or puerperal sepsis and intra-abdominal sepsis.
Skin and Soft Tissue Infections in particular cellulitis, animal bites and severe dental abscess with spreading cellulitis.

Dosage & administration: *Adults and children over 12 years*: The usual adult dose is one **Clamox®** 625 mg tablet every 12 hours or one **Clamox®** 375 mg tablet every 8 hours. For more severe infections and infections of the respiratory tract, the dose should be one **Clamox®** 625 mg tablet every 8 hours. The usual dose of Clamox 1 gm tablet is every 12 hourly.
Children: **Clamox®** 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 7.5 kg child would require 2 ml **Clamox®** suspension t.i.d. Treatment should not be extended beyond 14 days without review.
Clamox® DS suspension: *Child 2 months-2 years:* 0.15 ml/kg twice daily, doubled in severe infection.
Child 2-6 years (13-21 kg): 2.5 ml twice daily, doubled in severe infection.
Child 7-12 years (22-40 kg): 5 ml twice daily, doubled in severe infection.
Clamox® 0.6 gm Injection: **Clamox®** 0.6 gm can be administered intravenously 6 to 8 hourly by intravenous injection or intravenous infusion.
Clamox® 1.2 gm Injection: By intravenous injection over 3-4 minutes or by intravenous infusion, **Clamox®** 1.2 gm every 8 hours increased in more serious infections to 1.2 gm every 6 hours.

Contraindication: Penicillin hypersensitivity. Attention should be paid to possible cross-sensitivity with other ß lactam antibiotics, e.g. cephalosporins. A previous history of penicillin-associated jaundice/hepatic dysfunction.

Side effects: The incidence of adverse events, including drowsiness, is not dose related and is similar across subgroups defined by age, gender, and race. The other side effects are Viral infection (cold, flu), nausea, dysmenorrhea, fatigue, headache and throat irritation.

Use in pregnancy & lactation: Reproduction studies in animals (mice and rats) with orally and parenterally administered this combination have shown no teratogenic effects. In a single study in women with preterm, premature rupture of the foetal membrane (pPROM), it was reported that prophylactic treatment may be associated with an increased risk of necrotising enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician. It may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breast-fed infant.

Precautions: Dosage in renal impairment: Adults: Mild impairment (Creatinine clearance>30 ml/min): No change in dosage. Moderate impairment (Creatinine clearance 10-30 ml/min): One 625 mg tablet 12 hourly. Severe impairment (Creatinine clearance <10 ml/min): Not recommended.Dosage in hepatic impairment: Dose with caution; monitor hepatic function at regular intervals. There are, as yet, insufficient data on which to base a dosage recommendation. Administration: Oral: Tablets To minimise potential gastrointestinal intolerance, administer at the start of a meal. The absorption of Amoxicillin/Clavulanic is optimised when taken at the start of a meal. Duration of therapy should be appropriate to the indication and should not exceed 14 days without review.

Drug Interactions: Prolongation of bleeding time and prothrombin time has been reported in some patients receiving this combination. It should be used with care in patients on anti-coagulation therapy. In common with other broad-spectrum antibiotics, the combination may reduce the efficacy of oral contraceptives and patients 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 the combination and allopurinol.

Over dosage: Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. They may be treated symptomatically with attention to the water electrolyte balance. This combination may be removed from the circulation by haemodialysis. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

Storage: Store in a cool and dry place, protected from light.

Packaging
Clamox® 375 Tablet: Each carton contains 6X3 tablets in blister pack.
Clamox® 625 Tablet: Each carton contains 6X2 tablets in blister pack.
Clamox® 1 gm Tablet: Each carton contains 6X2 tablets in blister pack.
Clamox® 100 ml Powder for Suspension: Each carton contains 100 ml powder for suspension.
Clamox® DS 35 ml Powder for Suspension: Each carton contains 35 ml powder for suspension.
Clamox® 0.6 gm Injection: Each carton contains 1 vial of sterile drug mixture, 1 ampoule of water for injection (10 ml), 1 disposable syringe, 1 butterfly needle, alcohol prep. pad and first aid band.
Clamox® 1.2 gm Injection: Each carton contains 1 vial of sterile drug mixture, 2 ampoules of water for injection (10 ml each), 1 disposable syringe, 1 butterfly needle, alcohol prep. pad and first aid band.

Opsonin Pharma
Ideas for healthcare

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