For the use of a Registered Medical Practitioner, Hospital or a Laboratory)
Amoxycillin & Potassium Clavulanate Tablets BP 625mg

AEROCILLIN™ CV

Composition

Each film coated tablet contains
Amoxycillin Trihydrate BP
Eq. to Amoxycillin.....500mg
Potassium Clavulanate BP
(As Potassium Clavulanate diluted BP)
Eq. to Clavulanic acid.....125 mg
Excipients.....q.s.

Clinical pharmacology

Pharmacodynamics Spectrum: Amoxycillin and Potassium Clavulanate tablets is the group name for formulations containing 2, 4 and 5 parts of a broad spectrum penicillin, amoxycillin and 1 part of potassium clavulanate. Potassium clavulanate has been shown in vitro to be an irreversible inhibitor of beta-lactamases produced by: Staphylococcus aureus, Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Proteus vulgaris, Haemophilus influenzae, Neisseria gonorrhoea and Bacteroides fragilis. Potassium clavulanate does not inactivate the chromosomally mediated (Sykes Type 1 Cephalosporinase) beta-lactamases produced by Acinetobacter species, Citrobacter species, Enterobacter, Indole positive Proteus, Providencia species and Serratia marcescens. In vitro the formulation showed synergism against amoxycillin-resistant organisms, with no evidence of antagonism and the activity was not reduced in the presence of serum. (In vitro activity does not necessarily imply in vivo efficacy). Bactericidal action The amoxycillin component of the formulations exert a bactericidal action against many strains of Gram-positive and Gram-negative organisms. The clavulanic acid component has very little bactericidal action. It does however, by inactivation of susceptible betalactamases, protect amoxycillin from degradation by a large number of beta-lactamase enzymes produced by penicillin resistant strains of organisms.

Pharmacokinetics :

The pharmacokinetics of the two components of Amoxycillin and Potassium Clavulanate tablets are closely matched. Peak serum levels of both occur about one hour after oral administration. Absorption of Amoxycillin and Potassium Clavulanate tablets is optimised at the start of a meal. Both clavulanate and amoxicillin have low levels of serum binding; about 70% remains free in the serum. Doubling the dosage of Amoxycillin and Clavulanate potassium tablets approximately doubles the serum levels achieved.

Indications

Amoxycillin and Potassium Clavulanate tablet formulations are indicated for the treatment of infections caused by Amoxycillin resistant organisms producing beta-lactamases sensitive to Clavulanic acid: Upper respiratory tract, such as sinusitis, recurrent otitis media, tonsillitis. Lower respiratory tract, such as bronchitis (caused by amoxycillin resistant beta-lactamase producing Escherichia coli, Haemophilus influenzae andHaemophilus parainfluenzae), pneumonia. Urinary tract infections, such as cystitis, urethritis, pyelonephritis.

Skin and soft tissues.

Amoxycillin and Potassium Clavulanate tablet formulations will also be effective in the treatment of infections caused by amoxycillin sensitive organisms at the appropriate amoxycillin dosage since in this situation the clavulanic acid component does not contribute to the therapeutic effect.

Dosage And Administration

Usual dosages for the treatment of infection

Adults and children over 12 years In severe infections one Amoxycillin and Clavulanate potassium 625mg Tablets three times a day. Not recommended in children of 12 years and under. Dosage in renal impairment

Adults:

Mild impairment (Creatinine clearance>30 ml/min) Moderate impairment (Creatinine clearance 10- 30 ml/min)Severe impairment (Creatinine clearance <10 ml/min) No change in dosage One 625mg tablet 12 hourly 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 Amoxycillin and Clavulanate potassium tablets 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.

Side Effects And Special Precautions

The most frequently reported adverse effects are diarrhoea, nausea, vomiting, abdominal pain, skin rashes, urticaria and erythema multiforme, vaginitis, abnormal taste, headache, dizziness, tiredness and hot flushes. Hepatitis and cholestatic jaundice have been reported. The events may be severe, and occur predominantly in adult or elderly patients. Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased.

The hepatic events are usually reversible. However, in extremely rare circumstances, death has been reported. These have almost always been cases associated with serious underlying disease or concomitant medication. Gastro-intestinal - gastritis, stomatitis, glossitis, black 'hairy' tongue, enterocolitis and pseudomembranous colitis. If gastro-intestinal reactions are evident, they may be reduced by taking Amoxycillin and Clavulanate potassium tablet at the start of a meal.

Hypersensitivity - skin rashes, urticaria, erythema multiforme, rare cases of Stevens-Johnson syndrome and less frequently exfoliative dermatitis and toxic epidermal necrolysis have been reported. Whenever such reactions occur, Amoxycillin and Potassium Clavulanate tablet should be discontinued. Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic oedema can occur with oral penicillin (see warnings). Haematopoietic and lymphatic - Anaemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leucopenia and agranulocytosis have been reported during therapy with penicillins. These reactions are usually reversible on discontinuation

Precautions: Periodic assessment of organ system functions, including renal, hepatic and haematopoietic function, is advisable during prolonged therapy. Since Amoxycillin and Potassium Clavulanate tablet contains amoxycillin, an aminopenicillin it is not the treatment of choice in patients presenting with sore throat or pharyngitis because of the possibility that the underlying cause is infectious mononucleosis, in the presence of which there is a high incidence of rash if amoxycillin is used. Amoxycillin and Potassium Clavulanate tablet should be given with caution to patients with lymphatic leukaemia since they are especially susceptible to amoxycillin induced skin rashes. The possibility of superinfections with mycotic or bacterial pathogens should be kept in mind during therapy. If superinfections occur (usually involving Aerobacter, Pseudomonas or Candida), the agent should be discontinued and/or appropriate therapy instituted.

Impaired hepatic function - Changes in liver function tests have been observed in some patients receiving Amoxycillin and Potassium Clavulanate tablet. It should be used with care in patients with evidence of severe hepatic dysfunction.

Use in lactation - Amoxycillin is excreted in the milk; there is no data on the excretion of clavulanic acid in human milk. Therefore caution should be exercised when Amoxycillin and Potassium Clavulanate tablet is administered to a nursing woman.

Drug Interactions:

Probenecid decreases the renal tubular secretion of amoxycillin, but does not affect clavulanic acid excretion. Concomitant use with Amoxycillin and Clavulanate potassium tablet may result in increased and prolonged blood levels of amoxycillin but not of clavulanic acid. The concurrent administration of allopurinol and ampicillin substantially increases the incidence of skin rashes in patients receiving both agents as compared to patients receiving ampicillin alone. It is not known whether this potentiation of ampicillin rashes is due to allopurinol or the hyperuricaemia present in these patients. There is no data on Amoxycillin and Potassium Clavulanate tablet and allopurinol administered concurrently.

Overdosage

Nausea, vomiting and diarrhoea may occur with overdosing. Treatment is symptomatic and supportive. Amoxycillin may be removed from circulation by haemodialysis. The molecular weight, degree of protein binding and pharmacokinetic profile of clavulanic acid together with informatio from a single patient with renal insufficiency all suggest that this compound may also be removed by haemodialysis.

Storage And Handling Instructions: Store below 25°C. Protect from light.

Presentation: Amoxicillin and Potassium Clavulanate Tablet comes in a 10×10 Tablet Pack.

Shelf life: Refer to carton and strip.

Número de registro.:
Código neutral: HP/Drugs/09/92

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