Front

130 x 170mm

Back

CO-AMOXICLAV

ENDCLAV-625

625 mg FILM-COATED TABLET
ANTIBACTERIAL (PENICILLIN)

℞

FORMULATION:
Each film-coated tablet contains:
Amoxicillin Trihydrate BP
equivalent to Amoxicillin.....500 mg
Diluted Potassium Clavulanate BP
equivalent to Clavulanic Acid .....125 mg

PRODUCT DESCRIPTION:
White coloured, capsule shaped, biconvex, film-coated tablets with both sides plain.

PHARMACODYNAMIC PROPERTIES:
Mechanism of Action:
Co-Amoxiclav is a novel concept in antibiotic therapy. Resistance to many antibiotics is caused by bacterial enzymes which destroy the antibiotic before it can act on the pathogen. The Clavulanate anticipates this defense mechanism by blocking the ß-lactamase enzymes, thus rendering the organisms sensitive to Amoxicillin's rapid bactericidal effect of concentrations readily attainable in the body. Clavulanate by itself has little antibacterial activity, however, in association with Amoxicillin, it produces a novel antibiotic agent of broad spectrum with wide application in hospital and general practice.

Pharmacodynamics:
Co-Amoxiclav is bactericidal to a wide range of organisms including:
Gram-positive
Aerobes: *Enterococcus faecalis, Streptococcus pneumoniae, 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, *Escherichia coli, *Proteus mirabilis, *Proteus vulgaris, *Klebsiella species, *Moraxella catarrhalis,*
**Salmonella species, *Shigella species, Bordetella pertussis, Brucella species, *Neisseria gonorrhoeae, Neisseria meningitidis, Vibrio cholerae, Pasteurella multocida.*
Anaerobes: **Bacteroides spp. including B. fragilis.*
* Some members of these species of bacteria produce β-lactamase, rendering them insensitive to Amoxicillin alone.

PHARMACOKINETICS:
The pharmacokinetics of the two components of Co-Amoxiclav are closely matched. Peak serum levels of both occur about 1 hour after oral administration. Absorption of Co-Amoxiclav is optimized at the start of a meal.
Doubling the dosage of Co-Amoxiclav approximately doubles the serum levels achieved.
Both Clavulanate and Amoxicillin have low levels of serum binding; about 70% remains free in the serum.

INDICATIONS:
Indicated in the treatment such as infections of lower respiratory tract infection, otitis media, sinusitis, skin and skin structure infections and urinary tract infections.

DOSAGE & ADMINISTRATION:
Adults
The usual adult dose is 625 mg tablets of Co-Amoxiclav every 12 hours or one 375 mg tablet of Co-Amoxiclav every 8 hours. For more severe infections and infections of the respiratory tract, the dose should be one 1000 mg tablet of Co-Amoxiclav every 12 hours or one 625 mg tablet of Co-Amoxiclav every 8 hours. Patients with impaired renal function do not generally require a reduction in dose unless the impairment is severe.
Severely impaired patients with a glomerular filtration rate of <30 mL/min should not receive the 1000 mg tablet. Severely impaired patients with a glomerular filtration rate of 10 to 30 mL/min should receive 625 mg or 375 mg or every 12 hours, depending on the severity of the infection. Patients with less than 10 mL/min glomerular filtration rate should receive 625 or 375 every 24 hours, depending on severity of the infection.
Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals.

Pediatric Patients
Pediatric patients weighing 40 kg or more should be dosed according to the adult recommendations. Due to the different Amoxicillin to Clavulanic acid ratios in the 375 mg tablet of Co-amoxiclav versus 250 mg chewable tablet of Co-Amoxiclav, it should not be used until the pediatric patients weigh at least 40 kg or more.

Administration
Co-Amoxiclav may be taken without regard to meals; however, absorption of Clavulanate potassium is enhanced when Co-Amoxiclav is administered at the start of a meal. To minimize the potential for gastrointestinal intolerance, Co-Amoxiclav should be taken at the start of a meal or as directed by the physician.

CONTRAINDICATIONS:
A history of allergic reaction to ß-lactams (e.g., penicillins or cephalosporins) is a contraindication.
Co-Amoxiclav is contraindicated in patients with previous history of Co-Amoxiclav associated jaundice/hepatic dysfunction.

WARNINGS:
Drugs that delay peristalsis,(e.g., Opiates and Diphenoxylate with Atropine) may prolong and/or worsen the condition and should not be used.
Fluids, electrolytes, and protein replacement therapy should be provided when indicated.

PRECAUTION:
Co-Amoxiclav should be used with care in patients with evidence of hepatic dysfunction.

PREGNANCY AND LACTATION:
Use in Pregnancy:
There is limited experience of the use of Co-Amoxiclav in human pregnancy. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.

Use in Lactation:
Amoxicillin is excreted in breast milk; there are no data on the excretion of Clavulanic acid in human milk. Therefore, caution should be exercised when administering to a nursing woman.

ADVERSE DRUG REACTIONS:
Gastrointestinal Reactions: Gastritis, stomatitis, glossitis, black hair " tongue, indigestions, nausea, vomiting, diarrhea, enterocolitis, pseudomembranous colitis and candidiasis have been reported.
Hypersensitivity Reactions: Skin rashes and urticaria have been reported. These reactions may be controlled with antihistamines and if necessary, systemic corticosteroids. Rare cases of erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and an occasional case of exfoliative dermatitis have been reported. Interstitial nephritis can occur rarely . Serious and occasional fatal hypersensitivity (anaphylactic) reactions and angioneurotic edema have been reported in patients on penicillin therapy. Cross-sensitivity with other beta-lactam antibiotics eg. cephalosporins, may occur.
Hepatic Effects: As with some other agents, a few cases of transient hepatitis and cholestatic jaundice have been reported.
Haematologic Effects: Anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia and agranulocytosis have been reported during therapy with penicillins.

INTERACTIONS:
Following administration of Ampicillin to pregnant women, a transient decrease in plasma concentration of total conjugated Estriol, Cestadiol has been noted. This effect may also occur with Amoxicillin and therefore with Co-Amoxiclav. Probenecid decreases the renal tubular secretion of Amoxicillin but does not affect Clavulanic acid excretion. Concurrent use with Co-Amoxiclav may result in increased and prolonged blood levels of Amoxicillin but not to Clavulanic Acid. The concurrent administration of Allopurinol andAmpicillin increases substantially the incidence of rashes in patients receiving both medicines as compared to patients receiving Ampicillin alone. It is not known whether this potentiation of Ampicillin rashes is due to Allopurinol or the hyperuricemia present in these patients. No information is available about the concurrent use of Co-Amoxiclav and alcohol. However, the ingestion of alcohol while being treated with the beta-1 lactam antibiotics Latamoxef, Cefoperazone and Cephamandole has precipitated a disulfiram (Antabuse) like reaction in some patients. Therefore, the ingestion of alcohol should be avoided during and for several days after treatment with Co-Amoxiclav.

OVERDOSE AND TREATMENT:
Co-Amoxiclav may be removed from the circulation by hemodialysis.
Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident.
Gastrointestinal symptoms may be treated symptomatically with attention to the water electrolyte balance.
Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph.
Seek medical attention immediately at the first sign of any adverse drug reaction.

STORAGE CONDITION:
Store at temperatures not exceeding 30°C.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

AVAILABILITY:
Alu/Alu Blister Pack of 7's (Box of 14's)

DRP-5407
Date of First Authorization: July 30, 2014
Date of Revision of Package Insert: March 13, 2024

ENDURANCE HEALTHCARE PVT. LTD.

Manufactured by:
STALLION LABORATORIES PVT. LTD.
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Manufactured for:
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