규격: 100 * 220 mm
Color : K100 [redacted]

CO-AMOXICLAV

PENCLA

625 mg Film-Coated tablet

ANTIBACTERIAL

FORMULATION

Each Film-Coated tablet contains
Amoxicillin (as Trihydrate),USP ——— 500 mg
Clavulanate Potassium (as Clavulanic Acid),EP ——— 125 mg

DESCRIPTION

White or almost-white, oval film-coated tablet, scored on one side engraved with "KI" and "I", "AMC" on the other side.

PHARMACOKINETICS

Amoxicillin is resistant to inactivation by gastric acid. It is more rapidly and more completely absorbed than ampicillin when given by mouth. Peak plasma-amoxicillin concentrations of about 5 micrograms/mL have been observed 1 to 2 hours after a dose of 250 mg, with detectable amounts present for up to 8 hours.
Doubling the dose can double the concentration. The presence of food in the stomach does not appear to diminish the total amount absorbed. About 20% is bound to plasma proteins and plasma half-lives of 1 to 1.5 hours have been reported. The half-life may be prolonged in neonates, the elderly, and patients with renal impairment the half-life may be 7 to 20 hours. Amoxicillin is widely distributed at varying concentrations in body tissues and fluids. It crosses the placenta; small amounts are distributed into breast milk. Little amoxicillin passes into the CSF unless the meninges are inflamed.
Amoxicillin is metabolized to a limited extent to penicilloic acid which is excreted in the urine.
About 60% of an oral dose of amoxicillin is excreted unchanged in the urine in 6 hours by glomerular filtration and tubular secretion.
Urinary concentrations above 300 mcg/mL have been reported after a dose of 250 mg.

INDICATIONS

Co-amoxiclav is indicated for use in the treatment of infections caused by susceptible strains of microorganisms involved in the following:
Acute and chronic bronchitis, pneumonia, lung abscess, tonsillitis, sinusitis, otitis media, cystitis, urethritis, pyelonephritis, septic abortion, puerperal sepsis, chancroid, furunculosis, cellulitis, wound infection, intra-abdominal sepsis, osteomyelitis, and post-operative infections. Urinary tract infections.
Susceptible strains of microorganisms would include:
**Staphylococcus aureus, *Staphylococcus epidermidis, Streptococcus pneumoniae, Streptococcus pyogenes,* Viridans group *Streptococcus, *Enterococcus faecalis, *Enterococcus faecium, Corynebacterium spp., *Bacillus anthracis, Listeria monocytogenes, Clostridium spp., Peptococcus spp., Peptostre ptococcus spp.*
**Escherichia coli, *Proteus mirabilis, *Proteus vulgaris, *Klebsiella spp., *Salmonella spp., *Shigella spp. , Bordetella pertussis, *Yersinia enterocolitica, G ardnerella vaginalis, Brucella spp.,*
**Neisseria gonorrhea, *Moraxella catarrhalis, *Haemophilus influenzae, *Haemophilus ducreyi, Pasteurella multocida, Campylobacter jejuni, Vibrio Cholera, Helicobacter pylori, Legionella spp., *Bacteroides spp., *Fusobacterium spp.*
* - including β-lactamase producing strains which are resistant to ampicillin or amoxicillin

DOSAGE AND ADMINISTRATION

The usual adult oral dose is 375mg Film-Coated tablet three times daily or 625 mg Film-Coated tablet two times daily. For more severe infections or infections involving the respiratory tract, the dose is 625mg Film-Coated tablet three times daily or 1g tablet two times daily, or as prescribed by the physician.
The duration of treatment will depend on the severity of the infection but should generally be continued for at least 2 days after defervescence and disappearance of the signs and symptoms of infection.
The usual duration of treatment unless otherwise specified is 7 to 14 days.
Co-amoxiclav tablets should be swallowed whole without chewing to be taken with sufficient amounts of liquid without regard to meals.
Dosage adjustment is recommended among patients with impaired renal function as follows; no adjustment needed for creatinine clearance of >30 mL/min, 375 to 625 mg Film-Coated tablet daily for creatinine clearance of 10 – 30 mL/min, and 375 to 625 mg once daily for creatinine clearance of < 10 mL/min depending on the severity of the infection. The 1 g tablet of co-amoxiclav should not be used in patients with a glomerular filtration rate of <30 mL/min.
Or as prescribed by the physician.

CONTRAINDICATIONS

Co-amoxiclav is contraindicated in patients who have exhibited a history of hypersensitivity reaction to any penicillin. Co-amoxiclav is also contraindicated in patients with a history of penicillin-associated cholestatic jaundice or hepatic dysfunction.

PRECAUTIONS

Two of the 625 mg Film-Coated tablet shoud not be taken at one time since the double dose of clavunate is more likely to cause GIT adverse effect.
It should be administered carefully to the following patients:
1. Patients with severe hepatic dysfunction.
2. Patients with moderate or severe renal dysfunction. (Dose interval should be adjusted for the patients because blood concentration of the drug can be prolonged.)
3. Patients with a previous history of hypersensitivity to penicillins or cephems.
4. Patients who or whose family have a tendency to show allergic symptoms such as bronchial asthma, rashes, urticaria, etc.
5. Patients who are malnutritioned orally or who are parenterally nutritioned, the elderly patients, and patients with bad systemic condition. (Vitamin K deficiency may occur).

GENERAL PRECAUTION

1. Severe and occasionally fatal hypersensitivity (anaphylactic) reactions and vasculoneural edema may occur in patients treated with penicillin. Such reactions may easily occur in patients who have the previous sensitivity to multiple allergen or the previous penicillin hypersensitivity. Also these reactions may easily occur in both oral and parenteral therapy, but more frequently in parenteral therapy.
2. The long-term treatment with Co-Amoxiclav may result in overgrowth of non-susceptible organisms, thus careful observation is required for more than 14 days treatment.
3. Changes in liver function test have been observed in some patients receiving Co-Amoxiclav. The clinical significance of these changes is uncertain, but Co-Amoxiclav should be used with caution in patient with evidence of hepatic failure. Serious and usually reversible cholestatic jaundice have been reported rarely. Signs and symptoms may not occur in appearance until six weeks after treatment has ended.
4. In patients with moderate and severe renal dysfunction, dose of Co-Amoxiclav should be adjusted following "dosage and administration"
5. Erythematous rashes have been associated with glandular fever in patients receiving amoxicillin, thus use of Co-Amoxiclav should be avoided in case that glandular fever is suspected.

DRUG INTERACTION

1. Probenecid decreases the renal excretion of amoxicillin. Concurrent use with Co-Amoxiclav may result in increased and prolonged blood levels of amoxicillin.
2. The concurrent administration of allopurinol and ampicillin increases the incidence of rashes in patients receiving both drugs as compared to patients receiving ampicillin alone. But it is not know whether this potentiation of ampicillin rash is due to allopurinol or the yperuricemia present in these patients.
3. Co-Amoxiclav should not be co-administered with disulfiram.
4. Prolongation of bleeding time and prothrombin time has been reported in some patients receiving Co-Amoxiclav. Thus this drug should be used with care in patients on anticoagulation therapy.
5. Co-Amoxiclav may reduce the effect of oral contraceptives, and the caution should be given to patients.
6. Synergistic with aminoglycosides.
7. Erythema multiforme with amoxicillin after MMR vaccination.
8. Hypernatremia with Lithium.

ADVERSE EFFECTS

The most frequently reported adverse events are diarrhea, nausea and vomiting, skin rashes and urticaria, and vaginitis. Less frequent adverse events occurring in less than 1% of patients given co-amoxiclav include:
Hypersensitivity: Rarely urticaria and erythematous rashes may occur. Though erythematous rashes are usually mild and transient, hypersensitivity reactions may rarely be fatal. Gastrointestinal: Dyspepsia, flatulence, glossitis, stomatitis, mucocutaneous candidiasis and pseudomembranous enterocolitis may occur. Nausea, vomiting Skin: Rarely erythema multiforme, Stevens-Johnson syndrome, Lyell's syndrome, Quincke's edema and dermatitis may occur. If such cases are encountered, further administration of the drug should be curtailed.
Hepatic: Occasionally elevation of the serum transaminases may occur, however clinical hepatitis or cholestatic jaundice are rare and are reported more frequently in the elderly and in males. Liver dysfunctions are usually reversible but may be severe and very rarely, deaths have been reported but are usually associated with severe co-morbid diseases or with concomitant use of other drugs.
Renal: Rarely severe renal impairment such as acute renal failure and interstitial nephritis has been reported. Therefore, patients with suspected or potential renal problems should be carefully observed and periodically evaluated. If any abnormality is recognized, the drug should be discontinued and appropriate therapy instituted.
Hematologic: Hemolytic anemia, thrombocytopenia, eosinophilia, leucopenia, and agranulocytosis have been reported with penicillin therapy but are usually reversible on discontinuation of the drug.
Central Nervous System: Headache, agitation, anxiety, behavioral changes, confusion, convulsions, dizziness, and insomnia have been reported rarely.

USE IN PREGNANCY AND LACTATION

1. Animal studies have shown no teratogenic effects; however, safe use of Co-Amoxiclav during pregnancy has not been definitely established. Thus, this drug should be used during pregnancy only when the potential benefits justify the possible risks to the fetus. Especially, Co-Amoxiclav should not be administered during first trimester of pregnancy.
2. During lactation, trace quantities of penicillin can be excreted in breast milk.

OVERDOSAGE

Problems of overdosage with Co-Amoxiclav are unlikely to occur. As problems of overdosage, gastrointestinal disturbances or imbalance of body fluid or electrolytes may occur. In these cases, patients should be treated symptomatically with attention to water & electrolytes balance.
This drug may be removed by hemodialysis.

CAUTION

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

STORAGE

Store at temperatures not exceeding 25°C.

AVAILABILITY

Tropical Blister Pack x 4's (Box of 40's)

For suspected adverse drug reaction, report to the FDA : www.fda.gov.ph
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마지막 날짜 부분 확인 필요

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