ABROCLAV-625mg.TAB.

COMPOSITION :

Each film coated tablet contains :
Amoxicillin Trihydrate I.P.
Eq. to Amoxicillin 500mg.
Potassium Clavulanate Diluted I.P.
Eq. to Clavulanic Acid 125mg.

DESCRIPTION

AMOXICILLIN :

Amoxicillin is belong to semi synthetic penicillin group of antibiotic, it has a moderate spectrum, bactericidal, β-lactam antibiotic used to treat bacterial infections caused by susceptible pathogens. It is generally considered as the drug of choice within the semi synthetic penicillin because it is better absorbed, after oral administration, than other β-lactam antibiotics.

Amoxicillin is susceptible to β-lactamases-producing bacteria, which are resistant to a broad spectrum of β-lactam antibiotics, like penicillin. So, to enhance the stability and efficacy of Amoxicillin, combination of Clavulanate Potassium, a β-lactamases inhibitor is required with it.

The molecular formula of Amoxicillin is $C_{16}H_{19}N_3O_5S•3H_2O$.

Mechanism of action :

Amoxicillin acts by inhibiting the synthesis of bacterial cell walls. It inhibits cross-linkage between the linear peptidoglycan polymer chains which is a major component of the cell walls of both Gram +ive and Gram -ive bacteria.

Pharmacodynamic :

Half life (t1/2) : 1.27 hours.
MIC : 4 µg/mL.
Cmax : 10 µg/ml.
Tmax : 1 to 1.5 h.

Pharmacokinetic –

Absorption (Oral) : Amoxicillin is stable in the presence of gastric acid and is rapidly absorbed after oral administration. Food partially affects the absorption of amoxicillin orally administered. Amoxicillin is absorbed in the gut after oral administration.

Distribution : Amoxicillin diffuses readily into most body tissues and fluids, with the exception of brain and spinal fluid, except when meninges are inflamed. In blood serum, amoxicillin is approximately 20% protein-bound.

Metabolism : Metabolite through liver.

Oral bioavailability : >90%.

Excretion : Approximately 60% of an orally administered dose of amoxicillin is excreted in the urine within 6 to 8 hours.

Clavulanic acid : Clavulanic acid is a β-lactam drug that functions as a mechanism-based β-lactamase inhibitor. While not effective by itself as an antibiotic, when combined with penicillin-group antibiotics, it can overcome antibiotic resistance in bacteria that secrete β-lactamase, which otherwise inactivates most penicillins. Clavulanic acid is derived from the Streptomyces clavuligerus which produces clavulanic acid. With the β-lactam like structure, clavulanic acid looks structurally similar to penicillin .Chemical formula of Clavulanic acid is **$C_8H_9NO_5$.**

PHARMACOLOGY :

Pharmacodynamic :

Clavulanic acid has negligible intrinsic antimicrobial activity, despite sharing the β-lactam ring that is characteristic of β-Lactam antibiotics. However, the similarity in chemical structure allows the molecule to interact with the enzyme β-Lactamase secreted by certain bacteria to confer resistance to β-lactam antibiotics.

Pharmacokinetic :

Bioavailability : Well absorbed. The mean peak plasma concentration of clavulanic acid is 0.29 hour.

Metabolism : Hepatic .

Biological half life : Approximately 1 hour.

Excretion : Renal (30 – 40 %)

TAB. ABROCLAV-625 mg.

TAB. ABROCLAV-625 mg. is a combination of amoxicillin trihydrate, a β-lactam antibiotic, and potassium clavulanate, a β-lactamases inhibitor. This combination results to an increased spectrum of action and restored efficacy against amoxicillin-resistant bacteria that produce β-lactamases.
TAB. ABROCLAV-625 mg. is effective against some bacteria such as H. influenzae, N. gonorrhea, E. coli, Pneumococci, Streptococci, and certain strains of Staphylococci. Therefore, it is used to treat many infections such as sinusitis, pneumonia, dental infections, ear infections, bronchitis, urinary tract infections, and skin and soft tissue infections.

INDICATIONS :

TAB. ABROCLAV-625 mg. is indicated in the treatment of the following infections caused by susceptible micro-organisms to Amoxicillin-500 mg. & clavulanic acid-125 mg.-

Urinary Tract Infections (UTI) – Infected by E. coli, Klebsiella spp., and Enterobacter spp which produce β-lactamases.

Lower Respiratory Tract Infections (LRTI) – Infected by H. influenzae and M. catarrhalis that produce β-lactamases enzyme.

Skin and Skin Structure Infections – caused by β-lactamases–producing strains of S.aureus, E. coli, and Klebsiella spp.

Sinusitis –Infected by H. influenzae and M. catarrhalis that produce strains of β-lactamases.

Otitis Media – caused by β-lactamases– producing strains of H. influenzae and M. catarrhalis.

DOSES :

Adults

The usual adult dose of TAB. ABROCLAV-625 mg. is every 12 hours, for more severe infection and severe Respiratory Tract Infections it can be given 8 hourly. Patients with renal impaired function do not generally necessary a reduction in dose unless the impairment is severe.

Patients who are under Hem dialysis should receive TAB. ABROCLAV-625 mg. 24 hourly.
Patients with Hepatic disorder/impairment caution should be exercised and hepatic function should be monitored at regular intervals.

ADMINISTRATION :

TAB. ABROCLAV-625 mg. can be administered before or after meal, however if is taken at the start of a meal then absorption of clavulanate potassium is enhanced. Therefore, to minimize GIT disorder and to enhance the efficacy of Clavulanic potassium, TAB. ABROCLAV-625 mg. should be taken at the start of a meal.

SIDE EFFECTS :

TAB. ABROCLAV-625 mg. is generally well tolerated; however there is some mild/negligible adverse effect has been observed. The frequent observed side effects are skin rashes and urticaria, diarrhea, nausea and vomiting. Side effect like diarrhea or loose motion may occur when access or increase dose of TAB. ABROCLAV-625 mg. is administered. Some other less frequently observed adverse reactions are abdominal discomfort, flatulence, and headache.

DRUG INTERACTIONS :

Allopurinol, methotrexate, and oral contraceptives may cause negative drug interactions with amoxicillin and clavulanate potassium. When these interactions occur, the effectiveness of the medications may decrease and risk for side effects may increase.

PRECAUTIONS AND WARNINGS :

Special precautions should be taken with the patients suffering from liver disease, kidney disease or phenyl ketonuria before taking the antibiotic. Moreover, proper information should be collected from the patients regarding allergic sensitivity to penicillin.

A high percentage of patients with mononucleosis who receive Ampicillin develop an erythematosus skin rash. Thus, Ampicillin class of antibiotics should not be administered to patients with mononucleosis. There is possibility of super infections with mycotic or bacterial pathogens may occur during the therapy of TAB. ABROCLAV-625 mg. If super infections occur, the drug should be discontinued or appropriate therapy should be provided.

OVERDOSE :

In case of over dosage of TAB. ABROCLAV-625 mg. patients may experience initially GI symptoms like stomach and abdominal pain, vomiting and diarrhea. Rare case of rash, hyperactivity, or drowsiness may also be observed. If the symptoms are manifest due to overdose then TAB. ABROCLAV-625 mg. should be discontinued or appropriate treatment must be provided.

CONTRAINDICATIONS :

TAB. ABROCLAV-625 mg. is contraindicated in patients with a history of allergic reactions to penicillin.
TAB. ABROCLAV-625 mg. is also contraindicated in patients with a previous history of cholestatic jaundice or hepatic dysfunction.

STORAGE INSTRUCTIONS :

Store below 25◦ C, protected from light & moisture.

PRESENTATION :

Abroclav-625mg. tablet is available 1*6 in strip and 10 strips in a carton.