CO-AMOXICLAV

SOLCLAV

℞

500 mg /125 mg Film-coated Tablet
250 mg /62.5 mg per 5 mL Powder for Suspension
125 mg /31.25 mg per 5 mL Powder for Suspension
ANTIBACTERIAL

FORMULATION:
Each Film-coated Tablet contains:
Amoxicillin (as Trihydrate), USP .....500 mg
Clavulanic Acid (as Clavulanate Potassium), USP .....125 mg

Each 5 mL contains:
Amoxicillin (as Trihydrate), USP ..... 250 mg
Clavulanic Acid (as Clavulanate Potassium), USP .....62.5 mg

Each 5 mL contains:
Amoxicillin (as Trihydrate), USP .....125 mg
Clavulanic Acid (as Clavulanate Potassium), USP .....31.25 mg

PRODUCT DESCRIPTIONS:
Co-Amoxiclav (Solclav®) 500 mg Film-coated Tablet: White to off-white film coated tablet, biconvex, oval shape, plain on both sides, each containing 500 mg Amoxicillin and 125 mg Clavulanic acid.
Co-Amoxiclav (Solclav®) 250 mg /62.5 mg per 5 mL Powder for Suspension: Prepared by adding water to the powder to give an passion fruit flavor and white to off-white to yellowish-white suspension containing 250 mg Amoxicillin and 62.5 mg Clavulanic acid in each 5mL.
Co-Amoxiclav (Solclav®) 125 mg /31.25 mg per 5 mL Powder for Suspension: Prepared by adding water to the powder to give an orange flavored and white to off-white to yellowish-white suspension containing 125 mg Amoxicillin and 31.25 mg Clavulanic acid in each 5mL.

MECHANISM OF ACTION:
Amoxicillin acts through inhibition of biosynthesis of the bacterial cell wall mucopeptide. It is bactericidal against susceptible organisms during the stage of active multiplication. Amoxicillin is active against many
Gram-positive and Gram-negative pathogens. However, it is susceptible to degradation by beta-lactamases and therefore its spectrum does not include organisms which produce these enzymes.
Clavulanic acid is a beta lactam structurally related to the penicillins, found in micro-organisms resistant to penicillins.
The formulation of amoxicillin with clavulanic acid protects amoxicillin from degradation by beta-lactamase enzymes and effectively extends the antibiotic spectrum of amoxicillin to include many bacteria normally resistant to amoxicillin and other beta-lactam antibiotics.

PHARMACOKINETICS:
Amoxicillin and clavulanate potassium are both well absorbed after oral administration and are stable in the presence of gastric acid. Food does not affect the absorption and this combination product may given without regards to meals. The oral bioavailability of amoxicillin and clavulanic acid is approximately 90% and 75% respectively.
Clavulanic acid has about the same plasma elimination half-life (1 hr.) as that of amoxicillin (1.3 hrs.) Amoxicillin and clavulanic acid are widely distributed to most tissues and body fluids including peritoneal fluid, blister fluid, urine, pleural fluid, middle ear fluid, intestinal mucosa, bone, gallbladder, lungs, female reproductive tissues and bile. The penetration into CSF through non-inflamed meninges and into purulent bronchial secretions is low. Amoxicillin and clavulanic acid readily cross the placenta and are distributed into breast milk in low concentrations. Amoxicillin is bound to serum proteins to an extent of 17-20% while clavulanic acid is 20-30% bound to serum proteins. Approximately 10% of the dose of amoxicillin and less than 50% of dose of clavulanic are metabolized.
Amoxicillin and clavulanic acid are eliminated primarily unchanged through the renal route (glomerular filtration and tubular secretion). Approximately 50-78% of amoxicillin and 25-40% of clavulanic acid are excreted unchanged in urine within the first 6 hours after administration.

INDICATIONS:
Co-amoxiclav is indicated for the treatment of following infections caused by susceptible pathogens: lower respiratory tract infections, acute otitis media, sinusitis, urinary tract infections, skin and soft tissue infections.
Co-amoxiclav is also indicated for bacterial infections likely to be caused by amoxicillin-resistant beta-lactamase producing strains and that treatment should not usually exceed 14 days.
It is also considered for the following indications:
- recurrent tonsillitis
- acute exacerbations of chronic bronchitis, bronchopneumonia
- urinary tract infection especially recurrent & complicated but not prostatitis
- septic abortion, pelvic or puerperal sepsis & intra-abdominal sepsis
- cellulitis, animal bites and severe dental abscess with spreading cellulitis

DOSAGE AND ADMINISTRATION:
500 mg/ 125 mg Film Coated Tablet:
For more severe infections and infections of respiratory tract, the usual dosage is one tablet containing 500 mg of Amoxicillin and 125 mg of Clavulanic acid every 8 hours. Or as prescribed by the physician.

250 mg/ 62.5 mg per 5 mL Powder for Suspension:
7-10 years: 5 mL (1 teaspoonful) every 8 hours. Or as prescribed by the physician.

125 mg/ 31.25 mg per 5 mL Powder for Suspension:
7-12 years: 10 mL (2 teaspoonfuls) every 8 hours
2-6 years: 5 mL (1 teaspoonful) every 8 hours.
9 months- 1 year: 2.5 mL (1/2 teaspoon) every 8 hours. Or prescribed by the physician.

PRECAUTIONS:
Changes in liver function tests have been observed in some patients receiving Co-amoxiclav. Therefore dosage should reduced for patients with severe renal impairment. The clinical significance of these changes is uncertain but Co-amoxiclav should be used with caution in patients with evidence of hepatic dysfunction. Cholestatic jaundice, which may be severe, but is usually reversible, has been reported rarely. Signs and symptoms may not become apparent for up to six weeks after treatment ceased. Erythematous rashes have been associated with grandular fever in patients receiving amoxicillin. Co-amoxiclav should be avoided if grandular fever is suspected. Prolonged use may also occasionally result in overgrowth non-susceptible organisms.

CONTRAINDICATIONS:
A history of allergic reactions to beta-lactam antibiotics penicillin hypersensitivity, history of co-amoxiclav associate penicillin-associated jaundice or hepatic dysfunction.

ADVERSE EFFECTS:
Nausea, vomiting, diarrhea, rashes, rarely antibiotic associated colitis.

PREGNANCY AND LACTATION:
Reproduction studies in animals (mice and rats) with orally and parenterally administered Co-amoxiclav 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 with Co-amoxiclav may be associated with an increased risk of necrotizing enterocolitis in neonates. As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.
Co-amoxiclav may be administered during the period of lactation. With the exception of the risk of sensitization, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breast-fed infant.

DRUG INTERACTIONS:
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 of clavulanic acid.
Co-amoxiclav may reduce the efficacy of oral contraceptives and patients should be warned accordingly.
Penicillins such as co-amoxiclav may decrease the removal of methotrexate from the body increasing the risk of toxicity.
Antibiotics such as co-amoxiclav may alter the effect of anticoagulants such as warfarin.

OVERDOSE AND TREATMENT:
Cases of overdosages are usually asymptomatic. 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. Co-amoxiclav may be removed from the circulation by haemodialysis.
During the administration of high doses of co-amoxiclav, adequate fluid intake and urinary output should be maintained to minimize the possibility of amoxicillin crystalluria.
Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

DIRECTION FOR RECONSTITUTION:
125 mg/31.25 mg & 250 mg/62.5 mg per 5 mL Powder for Suspension:
To make 60 mL reconstituted suspension, mix thoroughly the contents with 50 mL cooled water and shake well until the powder is evenly suspended. After reconstitution, suspension is stable for 7 days under refrigeration (2-8°C).

CAUTION:
Foods, Drugs, Devices and Cosmetics Acts prohibits dispensing without prescription.
ADR REPORTING STATEMENT:
"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 below 25°C. Shake well before using.

AVAILABILITY:
500 mg / 125 mg Film-coated Tablet
Foil Strip x 10's (Box of 30's)

125 mg/31.25 mg per 5 mL Powder for Suspension
250 mg/62.5 mg per 5 mL Powder for Suspension
Plastic bottle- Bottle of 60 mL

REGISTRATION NUMBER:
Co-Amoxiclav (Solclav®) 500 mg / 125 mg Film-coated Tablet: DRP-615-06
Co-Amoxiclav (Solclav®) 125 mg/31.25 mg per 5 mL Powder for Suspension: DR-XY39979
Co-Amoxiclav (Solclav®) 250 mg/62.5 mg per 5 mL Powder for Suspension: DRP-294-07

DATE OF FIRST AUTHORIZATION:
Co-Amoxiclav (Solclav®) 500 mg / 125 mg Film-coated Tablet: 4 November 2008
Co-Amoxiclav (Solclav®) 125 mg/31.25 mg per 5 mL Powder for Suspension: 1 September 2011
Co-Amoxiclav (Solclav®) 250 mg/62.5 mg per 5 mL Powder for Suspension: 18 November 2010

REVISION DATE:
September 2021

Manufactured by:
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