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Rx

Co-Amoxiclav

VICLA15-var (PHIL)

Clamovid
Antibacterial

Description
Co-Amoxiclav (Clamovid) 500 mg/125 mg Tablet - Oblong, white, film-coated tablet with shallow convex faces.
Co-Amoxiclav (Clamovid) Powder for Suspension - White to yellowish powder for suspension.

Formulation
Co-Amoxiclav (Clamovid) 500 mg/125 mg Tablet - Amoxicillin (as trihydrate) 500 mg/tablet, Clavulanic Acid (as potassium clavulanate 125 mg/tablet).
Co-Amoxiclav (Clamovid) Powder for Suspension - Amoxicillin (as trihydrate) 125 mg/5 mL, Clavulanic Acid (as potassium clavulanate) 31.25 mg/5 mL

Pharmacologic Action
Amoxicillin is a broad-spectrum bactericidal antibiotic which exerts its killing action on growing and dividing bacteria by inhibiting bacterial cell wall synthesis. The spectrum of activity of amoxicillin may be extended by the concomitant use of beta lactamase inhibitor such as clavulanic acid. In combination the activity of amoxicillin is enhanced against several species not generally considered sensitive. These have included Bacteroides, Legianella & Nocardia species and *Bukholderia pseudomallei (Pseudomonas pseudomallei)*

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 5µg per 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 concentraton. The presence of food in the stomach does not appear to diminish the total amount absorbed.
About 20% is bound to plasma proteins in the circulation and plasma half-lives of 1 to 1.5 hours have been reported. The half-life may be longer in neonates and the elderly; in renal failure 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 metabolised 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 µg per mL have been reported in bile; some may be excreted in he faeces.
Amoxicillin with clavulanic acid. The pharmacokinetics of amoxicillin and clavulanic acid are broadly similar and neither appears to affect the other to any great extent.

Indications
For the treatment of acute otitis media, sinusitis, pneumonia, skin and soft tissue infections, urinary tract infections caused by beta-lactamase-producing strains of bacteria.

Contraindications
- Contraindicated in patients known to be hypersensitive to penicillin. Attention should be paid to possible cross-sensitivity with other beta-lactam antibiotics e.g. cephalosporins.
- Contraindicated in patients with a previous history of penicillin-associated jaundice/hepatic dysfunction.
- Contraindicated in patients with infectious mononucleosis.

Precautions/Warnings
- Patients sensitive to one penicillin may be allergic to other penicillins or related antibiotics such as cephalosprins, cephamycins or penicillamine.
- Caution in patients with history of allergy such as asthma, eczema, hay fever or hives.
- Caution in patients with a history of bleeding disorders.
- Caution in patients with a history of gastrointestinal disease especially ulcerative colitis, regional enteritis or antibiotic associated colitis.
- Caution in patients with impaired renal function. Adjustment of dosage may be necessary.
- Use with caution in patients with hepatic dysfunction as changes in liver function tests have been observed.
- Erythematous rashes have been associated with glandular fever in patients receiving amoxycillin.
- Prolonged use may also occasionally result in overgrowth of non-susceptible organisms. Transferable resistance has been reported in H.pylori.

Use in Pregnancy and Lactation
- Use should be avoided in pregnancy, especially in the first trimester, unless considered essential by the physician.
- Co-Amoxiclav (Clamovid) may be administered during the period of lactation. With the exception of the risk of sensitisation, associated with the excretion of trace quantities in breast milk, there are no known detrimental effects for the breast-fed infant.

Adverse Effects
Side effects are uncommon and mainly of a mild and transitory nature.

- Gastrointestinal effects : Diarrhoea, indigestion, nausea, vomiting and mucocutaneous candidiasis have been reported. Taking Co-Amoxiclav (Clamovid) at the start of meals may reduce them.
- Genito-urinary effects : Vaginal itching, soreness and discharge.
- CNS effects : Convulsions may occur with impaired renal function or in those receiving high doses.
- Hepatic effects : Moderate and symptomatic rises in AST and / or ALT and alkaline phosphatase have been reported occassionally. Hepatitis and cholestatic jaundice have been reported rarely. These hepatic reactions have been reported more commonly with Co-Amoxiclav (Clamovid) than with other penicillins.
- Hypersensitivity reactions : Urticarial and erythematous rashes sometimes occur. Rarely erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative dermatitis, serum sickness-like syndrome and hypersensitivity vasculitis have been reported. Treatment should be discontinued if one of these disorders occurs.
- Haematological effects : As with other beta-lactams, transient leucopenia, thrombocytopenia and haemolytic anaemia have been reported rarely. Prolongation of time and prothrombin time has also been reported rarely.

Drug Interactions

- Concurrent use of Co-Amoxiclav (Clamovid) with anticoagulants may cause prolongation of bleeding time and prothrombin time. Patients should be monitored carefully for signs of bleeding.
- Co-Amoxiclav (Clamovid) may reduce the efficacy of oral contraceptives. An alternate or additional method of contraception should be used while taking Co-Amoxiclav (Clamovid).
- Concomitant use of Co-Amoxiclav (Clamovid) with allopurinol can increase the likelihood of allergic reactions, especially in hyperuricaemic patients.
- Concurrent use with probenecid will decrease renal tubular excretion of amoxycillin and this requires careful monitoring.
- Bacteriostatic antibiotics such as chloramphenicol, erythromycins, sulphonamides and tetracyclines may interfere with the bactericidal effect of Co-Amoxiclav (Clamovid).

Overdosage

Clinical features : Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident.

Treatment for overdosage
Since there is no specific antidote, overdosage may be treated symptomatically with attention to the water electrolyte balance. Co-Amoxiclav (Clamovid) may be removed from the circulation by haemodialysis.

Dosage and Administration

Co-Amoxiclav (Clamovid) 500 mg/125 mg Tablet
Adults and Children Over 12 years old:

Severe infections : Oral, one tablet, three times a day.

Other infections : Oral, one tablet, two times a day.

Dosage in Renal Impairment:
Adults : Mild impairment (Creatinine clearance > 30 ml/min) : No change in dosage.
: Moderate impairment (Creatinine clearance 10 - 30 ml/min) : One tablet, 12 hourly.
: Severe impairment (Creatinine clearance < 10 ml/min) : 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.

Note : Not recommended in children of 12 years and under.

Co-Amoxiclav (Clamovid) 125 mg/ 31.25 mg/ 5 mL Powder for Suspension
The usual recommended daily dosage is 25 mg/Kg/day in divided doses every 8 hours. In more serious infections the dosage may be increased up to 50 mg/Kg/day in divided doses every eight hours.

Children:
1 to 6 years (10 to 18 Kg) : Oral 5 mL (approximately 125 mg of Amoxicillin and 31.25 mg of Clavulanic Acid) every eight hours.
Children up to 10 years : 1 - 2 teaspoonfuls every 8 hours.

Duration of therapy should be appropriate to the indication and should not exceed 14 days without review or as prescribed by the physician.

Direction for Reconstitution
To reconstitute, fill half of the bottle with water. Replace cap and shake the bottle untill all of the powder is suspended. Allow to stand for 5 minutes. Add more water until the 100ml mark. Shake again. Reconstituted product should be kept refrigerated and is stable for 7 days.

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.

Co-Amoxiclav (Clamovid) 500mg/125mg Tablet

Storage	: Store at temperatures not exceeding 25°C. Protect from light and moisture.
Availability	: Tablet 625 mg x Alu-Alu Blister Pack x 5's (Box of 15's)
Registration Number	: DR-XY30767
Date of Renewal of Authorization	: January 17, 2020

Co-Amoxiclav (Clamovid) Powder for Suspension

Storage	: Store at temperatures not exceeding 25°C. Protect from light and moisture.
Availability	: Powder for Suspension 125 mg/31.25 mg/ 5ml x Type III Amber Glass Bottle with Plastic Measuring Spoon x 100 ml (Box of 1)
Registration Number	: DR-XY30772
Date of Renewal of Authorization	: April 22, 2020

Manufacturing by	: Bilim Pharmaceuticals, Çerkezköy Organize Sanayi Bölgesi, Karaağac, Mh, 5. Sk. No. 6, Kapaklı-Tekirdağ 59510, Turkey.
For	: HOVID Bhd., 121, Jalan Tunku Abdul Rahman, 30010 Ipoh, Malaysia.
Imported & Distributed by	: HOVID Inc., Unit B, 7th Floor, Karina Building, 33 Shaw Boulevard, Pasig City, Philippines.
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