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PHARMACODE

CLAMOVID BID GRANULES
CLAMOVID BID FORTE GRANULES

BILIM SAP Code
VICLA24-1 (MY)

DESCRIPTION
Granules : Creamy, white coloured homogenous powder.

COMPOSITION
Clamovid BID Granules

Amoxicillin (as trihydrate)	200 mg/5 mL
Clavulanic Acid (as potassium clavulanate)	28 mg/5 mL

Clamovid BID Forte Granules

Amoxicillin (as trihydrate)	400 mg/5 mL
Clavulanic Acid (as potassium clavulanate)	57 mg/5 mL

Pharmacodynamics
Amoxicillin is a beta-lactam antibiotic that has bactericidal activity against the commonly occurring bacterial pathogens. It exerts its killing action on growing and dividing bacteria by inhibiting bacterial cell-wall synthesis. As an aminopenicillin it can penetrate the outer membrane of some Gram-negative bacteria, which renders a broader spectrum of activity. However, it is inactivated by beta-lactamase, which is responsible for the resistance in some species.

Clavulanic acid by itself has little antibacterial activity. However, in combination with amoxicillin, it extends the spectrum of amoxicillin to cover a wider range of organisms, including many resistant to other β-lactam antibiotics. The clavulanic aid blocks this β-lactamase enzyme rendering the organisms susceptible to amoxicillin's rapid bactericidal effects at concentrations readily attainable in the body.

Pharmacokinetics
The pharmacokinetics of amoxicillin and clavulanic acid is closely matched.

Absorption
Amoxicillin is resistant to inactivation by the acid of gastric secretions, the absorption of Clamovid is optimized at the start of a meal. Peak plasma concentrations of both achieved about 1 to 2 hours after oral administration; the present of food does not appear to diminish the total amount absorbed.

Distribution
Amoxicillin is widely distributed at varying concentrations in body tissues and fluid. It crosses the placenta and small amounts are excreted in breast milk. Little amoxicillin passes into the CSF unless meninges are inflamed.

Protein Binding
Both clavulanate and amoxicillin have low levels of serum protein binding; about 70% remain free in the serum.

Metabolism
Amoxicillin is metabolized to a limited extent to penicilloic acid, clavulanate may be metabolized more extensively than amoxicillin.

Excretion
Both components of Clamovid have half-lives of approximately 1 hour. The half-life may be longer in neonates and the elderly; in renal failure half-lives have been 7 to 20 hours. About 60% of both are excreted unchanged within 6 hours of oral administration by glomerular filtration and tabular secretion. Probenecid retards renal excretion of amoxicillin but not clavulanate suggesting that clavulanate is cleared predominantly by glomerular filtration. Clearance of clavulanate decreases with decreasing renal function, but not to the same extent as for amoxicillin. Both amoxicillin and clavulanate are removed by heamodialysis. High concentration of amoxicillin has been reported in bile; some may be excreted in the feaces.

INDICATIONS
For treatment of acute otitis media, sinusitis, pneumonia, skin and soft tissues infections, urinary tract infections caused by beta-lactamase-producing 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.

WARNINGS AND PRECAUTIONS
- Patients sensitive to one penicillin may be allergic to other penicillins or related antibiotics such as cephalosporins, cephamycins or beta-lactamase inhibitors.
- 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 amoxicillin.
- Prolonged use may also occasionally result in overgrowth of non-susceptible organisms.
- Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients receiving therapy with beta-lactams. Before initiating therapy with CLAMOVID, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, CLAMOVID must be discontinued immediately and appropriate alternative therapy instituted.

USE IN PREGNANCY AND LACTATION
- Use should be avoided in pregnancy, especially in the first trimester, unless considered essential by the physician.

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- 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.

SIDE/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 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 asymptomatic rises in AST and/or ALT and alkaline phosphatase. The risk increases with duration of treatment longer than 14 days.
- Hypersensitivity reactions : Urticarial and erythematous skin rashes, angioedema and anaphylaxis have been reported. Treatment should be discontinued if one of these symptoms occurs.
- Haematological effects : As with other beta-lactams, transient leucopenia, thrombocytopenia and haemolytic anaemia have been reported rarely.
- Skin and subcutaneous tissue disorders : (Frequency "very rare") Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

DRUG INTERACTIONS

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

OVERDOSE

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

Treatment for overdose:
Since there is no specific antidote, overdose may be treated symptomatically with attention to the water electrolyte balance. Clamovid may be removed from the circulation by haemodialysis.

DOSAGE AND ADMINISTRATION

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 70ml mark. Shake again.

GRANULES

Paediatric dosing
3 months - 2 years : Dosing should be calculated strictly according to body weight.

The usual recommended daily dosage is:
In mild to moderate infections : Oral, 25mg/kg/day
In more severe infections : Oral, 45mg/kg/day

Daily dosage should be divided into equal doses and administered every 12 hours.
Clamovid Granules are not recommended for children with immature kidney function and renal impairment with glomerular filtration rate < 30mL/min.

CLAMOVID BID GRANULES

Mild to moderate infections
2 to 6 years (13 to 21 kg) : Oral, 5mL every 12 hours
7 to 12 years (22 to 40 kg) : Oral, 10mL every 12 hours

Severe infections
2 to 6 years (13 to 21 kg) : Oral, 10mL every 12 hours

CLAMOVID BID FORTE GRANULES

Mild to moderate infections
2 to 6 years (13 to 21 kg) : Oral, 2.5mL every 12 hours
7 to 12 years (22 to 40 kg) : Oral, 5mL every 12 hours

Severe infections
2 to 6 years (13 to 21 kg) : Oral, 5mL every 12 hours
7 to 12 years (22 to 40 kg) : Oral, 10mL every 12 hours

Duration of therapy should be appropriate to the indication and should not exceed 14 days without review.

Storage : Store below 30°C. Protect from light and moisture. Refrigerate after reconstitution, to store between 2 - 8°C. Use within 7 days after reconstitution.
Presentation/Packing : Granules 228mg/5mL x amber glass bottle of 70mL
: Granules 457mg/5mL x amber glass bottle of 70mL

Product Registration Holder (Malaysia)/
Marketing Authorisation Holder/ Product Owner: **HOVID Bhd.**
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30010 Ipoh, Perak, Malaysia.

Manufactured by: BILIM ILAC SANAYII VE TICARET A.S.
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