Lactation
Both substances are excreted into breast milk (nothing is known of the effects of clavulanic acid on the breast-fed infant).
Consequently, diarrhea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breast-feeding might have to be discontinued. Amoxicillin/clavulanic acid should only be used during breast-feeding after benefit/risk assessment by the physician in charge.

Side effects:
Infections and infestations.
Common: Mucocutaneous Candidiasis.
Blood and lymphatic system disorders.

Rare: Reversible leucopenia (including neutropenia) and thrombocytopenia
Very rare: Reversible agranulocytosis and hemolytic anemia. Prolongation of bleeding time and prothrombin time (see warning and precautions).

Immune system disorders
Very rare: angioneurotic oedema, anaphylaxis, serum sickness-like syndrome, hypersensitivity vasculitis nervous system disorders.
Uncommon: dizziness, headache.
Very rare: Reversible hyperactivity and convulsions, convulsions may occur in patients with impaired renal function or in those receiving high doses.

Gastrointestinal disorders:
Adults:
Very common: diarrhea
Common: Nausea, vomiting.

Children:
Common: Diarrhea, Nausea, vomiting.

All populations:
Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking Cledomox at the start of a meal.

Uncommon: Indigestion
Very rare: Antibiotic – associated colitis (including pseudomembranous colitis and hemorrhagic colitis). Black hairy tongue.

Hepatobiliary disorders:
Uncommon: A moderate rise in AST and / or ALT has been noted in patients treated with bet-lactam class antibiotics, but the significance of these finding is unknown.

Very rare: hepatitis and cholestatic jaundice. These events have been noted with other penicillins and cephalosporin.

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment.
These events have been very rarely reported in children.
Signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible. Hepatic events may e severe and in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.

Skin and subcutaneous tissue disorders.
Uncommon: Skin rash, pruritus, urticaria
Rare: Erythema multiforme.
Very Rare: Stevens- Johnson syndrome, toxic epidermal necrolysis, bullous exfoliative- dermatitis, acute generalized exanthemous pustulosis (AGEP)
If any hypersensitivity dermatitis reaction occurs, treatment should be discontinued.
Frequency 'very rare': Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)

Renal and Urinary disorders.
Very Rare: Interstitial nephritis, crystlluria (see over dose).

Overdose:
Symptoms and signs of overdose
Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Amoxicillin crystalluria, in some cases leading to renal failure, has been observed.

Convulsions may occur in patients with impaired renal function or in those receiving high doses.
Amoxicillin has been reported to precipitate in bladder catheters, predominantly after intravenous administration of large doses. A regular check of patency should be maintained.

Treatment of intoxication
Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance.
Amoxicillin/clavulanic acid can be removed from the circulation by hemodialysis.

Presentation:
DOSAGE FORM AND PACKAGING AVAILABLE
Cledomox 625 tablets: Pack of 10x10's AluAlu Blister Pack.

Packing description: 10 tablets are packed in a plain Alu-Alu foil and Printed aluminium blister foil.
Such 10 blisters are packed in printed carton with a package insert.

Storage Information:
Store in below 30°C & protect from light.
Keep Medicine out of reach of children.

Shelf life:
24 months

Product Registration Holder:
Zulat Pharmacy Sdn Bhd,
No.23 & 23A, Jalan Bandar 3, Taman Melawati 53100, Kuala Lumpur, Malaysia.

Manufactured By:
Medopharm Private Limited,
50, Kayarambedu Village, Guduvanchery - 603 202, India.

Date of information: Oct, 2025

PENC0730/05

DUMMY

CLEDOMOX 625 mg TABLET

CO-AMOXICLAV TABLETS BP

Composition:

CLEDOMOX 625
Each film-coated tablet contains:
Amoxicillin Trihydrate BP 574.05mg is equivalent to Amoxicillin 500 mg
Diluted Potassium Clavulanate BP ..297.87mg
(Diluted Potassium Clavulanate contains 148.937mg Potassium Clavulanate
(equivalent to 125mg Clavulanic acid) + Avicel Blend (microcrystalline cellulose) …148.937mg

Description:
CLEDOMOX625: White or off white oval shape film coated tablets plain on both sides.

Pharmacodynamics:
Amoxicillin is semisynthetic penicillin (beta-lactam antibiotic) that inhibits one or more enzymes (often referred to as penicillinbinding proteins, PBPs) in the biosynthetic pathway of bacterial peptidoglycan, which is an integral structural component of the bacterial cell wall. Inhibition of peptidoglycan synthesis leads to weakening of the cell wall, which is usually followed by cell lysis and death.
Amoxicillin is susceptible to degradation by beta-lactamases produced by resistant bacteria and therefore the spectrum of activity of amoxicillin alone does not include organisms which produce these enzymes.
Clavulanic acid is a beta-lactam structurally related to penicillin. It inactivates some beta-lactamase enzymes thereby preventing inactivation of amoxicillin. Clavulanic acid alone does not exert a clinically useful antibacterial effect.
PK/PD relationship
The time above the minimum inhibitory concentration (T>MIC) is considered to be the major determinant of efficacy for amoxicillin.
Mechanisms of resistance
The two main mechanisms of resistance to amoxicillin/clavulanic acid are:
- Inactivation by those bacterial beta-lactamases that are not themselves inhibited by clavulanic acid, including class B, C and D.
- Alteration of PBPs, which reduce the affinity of the antibacterial agent for the target.

Impermeability of bacteria or efflux pump mechanisms may cause or contribute to bacterial resistance, particularly in Gram-negative bacteria.
Commonly susceptible species

Aerobic Gram-positive micro-organisms
Enterococcus faecalis
Gardnerella vaginalis
Staphylococcus aureus (methicillin-susceptible)
Coagulase-negative staphylococci (methicillin-susceptible)
Streptococcus agalactiae
Streptococcus pneumoniae[1]
Streptococcus pyogenes and other beta-hemolytic streptococci
Streptococcus viridans group

Aerobic Gram-negative micro-organisms
Capnocytophaga spp.
Eikenella corrodens
Haemophilus influenzae[2]
Moraxella catarrhalis
Pasteurella multocida

Anaerobic micro-organisms
Bacteroides fragilis
Fusobacterium nucleatum
Prevotella spp.

Species for which acquired resistance may be a problem
Aerobic Gram-positive micro-organisms
Enterococcus faecium

Aerobic Gram-negative micro-organisms
Escherichia coli
Klebsiella oxytoca
Klebsiella pneumoniae
Proteus mirabilis
Proteus vulgaris
Inherently resistant organisms:
Aerobic Gram-negative micro-organisms
Acinetobacter sp.
Citrobacter freundii
Enterobacter sp.
Legionella pneumophila
Morganella morganii
Providencia spp.
Pseudomonas sp.
Serratia sp.
Stenotrophomonas maltophilia

Other micro-organisms
Chlamydophila pneumoniae
Chlamydophila psittaci
Coxiella burnetti
Mycoplasma pneumoniae

Pharmacokinetics:
Absorption
Amoxicillin and clavulanic acid, are fully dissociated in aqueous solution at physiological pH. Both components are rapidly and well absorbed by the oral route of administration. Absorption of amoxicillin/clavulanic acid is optimized when taken at the start of a meal.
Following oral administration, amoxicillin and clavulanic acid are approximately 70% bioavailable. The plasma profiles of both components are similar and the time to peak plasma concentration (Tmax) in each case is approximately one hour.
Amoxicillin and clavulanic acid serum concentrations achieved with amoxicillin/clavulanic acid are similar to those produced by the oral administration of equivalent doses of amoxicillin or clavulanic acid alone.

Distribution
About 25% of total plasma clavulanic acid and 18% of total plasma amoxicillin is bound to protein. The apparent volume of distribution is around 0.3-0.4 l/kg for amoxicillin and around 0.2 l/kg for clavulanic acid.
Following intravenous administration, both amoxicillin and clavulanic acid have been found in gall bladder, abdominal tissue, skin, fat, muscle tissues, synovial and peritoneal fluids, bile and pus. Amoxicillin does not adequately distribute into the cerebrospinal fluid.
From animal studies there is no evidence for significant tissue retention of drug-derived material for either component. Amoxicillin, like most penicillins, can be detected in breast milk. Trace quantities of clavulanic acid can also be detected in breast milk.
Both amoxicillin and clavulanic acid have been shown to cross the placental barrier.
Biotransformation
Amoxicillin is partly excreted in the urine as the inactive penicilloic acid in quantities equivalent to up to 10 to 25% of the initial dose.
Clavulanic acid is extensively metabolized in man and eliminated in urine and faeces and as carbon dioxide in expired air.
Elimination
The major route of elimination for amoxicillin is via the kidney, whereas for clavulanic acid it is by both renal and non-renal mechanisms.
Amoxicillin/clavulanic acid has a mean elimination half-life of approximately one hour and a mean total clearance of approximately 25 l/h in healthy subjects. Approximately 60 to 70% of the amoxicillin and approximately 40 to 65% of the clavulanic acid are excreted unchanged in urine during the first 6 h after administration of single Co-amoxiclav 250 mg/125 mg or 500 mg/125 mg tablets. Various studies have found the urinary excretion to be 50-85% for amoxicillin and between 27-60% for clavulanic acid over a 24 hour period. In the case of clavulanic acid, the largest amount of drug is excreted during the first 2 hours after administration.
Concomitant use of probenecid delays amoxicillin excretion but does not delay renal excretion of clavulanic acid.
Age
The elimination half-life of amoxicillin is similar for children aged around 3 months to 2 years and older children and adults. For very young children (including preterm newborns) in the first week of life the interval of administration should not exceed twice daily administration due to immaturity of the renal pathway of elimination. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.
Gender
Following oral administration of amoxicillin/clavulanic acid to healthy males and female subjects, gender has no significant impact on the pharmacokinetics of either amoxicillin or clavulanic acid.
Renal impairment
The total serum clearance of amoxicillin/clavulanic acid decreases proportionately with decreasing renal function. The reduction in drug clearance is more pronounced for amoxicillin than for clavulanic acid, as a higher proportion of amoxicillin is excreted via the renal route. Doses in renal impairment must therefore prevent undue accumulation of amoxicillin while maintaining adequate levels of clavulanic acid.
Hepatic impairment
Hepatically impaired patients should be dosed with caution and hepatic function monitored at regular intervals.

Indications:
Cledomox is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The β-lactamase inhibitory action of clavulanate extends the spectrum of Amoxicillin to embrace a wider range of organisms including many resistant to other β-lactama antibiotics.
Cledomox should be used in accordance with local official Antibiotic-Prescribing guidelines and local susceptibility data.

Cledomox oral presentation for twice daily dosing, are indicated for short-term treatment of bacterial infections at the following sites:
Upper respiratory tract infections (including ENT) e.g. Tonsillitis, sinusitis, otitis media.
Lower respiratory tract infections e.g. acute exacerbation of chronic bronchitis, lobar and bronchopneumonia.
Genito- Urinary tract infections, e.g. Cystitis, urethritis, phelonephritis.
Skin and soft tissue infections, e.g. boils, abscesses, cellulitis, wound infections.
Bone and joint infections e.g. osteomyelitis.
Dental infections e.g. dnetoalveolar abscess
Other infections e.g. Septic abortion, puerperal sepsis, intra-abdominal sepsis.

Susceptibility to Cledomox will vary with geography and time (see Pharmacological Properties, Pharmacodynamics for further information). Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

Dosage and Administration:
"Cledomox 625mg tablet is available in only one strength of 625mg (Amoxicillin 500mg + Clavulanic acid 125mg). Cledomox is not able to deliver all approved dose regimens of Amoxicillin + Clavulanic acid; other approved dosage forms and strengths of Amoxicillin + Clavulanic acid should be used in such cases".

Usual dosages for the treatment of infection.
Adults and children over 12 years.

Mild- moderate infections: One Cledomox 625mg tablet twice daily.
Severe infections: One Amoxicillin 875mg + Clavulanic acid 125mg Tablet twice daily.

Dosage in dental infections (e.g. dentoalveolar abscess)
Adults and children over 12 years: one cledomox 625mg tablet twice daily for 5 days
Cledomox 625mg tablet and Amoxicillin 875mg + Clavulanic acid 125mg tablet are not recommended in children of 12 years and under

Dosage in renal impairment:
Adults
The Amoxicillin 875mg + Clavulanic acid 125mg Tablet should only be used in patients with a glomerular filtration rate of >30ml/min.

Mild impairment (creatinine clearance >30 ml /min)	Moderate impairment (creatinine clearance 10-30 ml/min)	Severed impairment creatinine clearance ,10ml/min)
No change in dosage (i.e. either one 625mg tablet twice daily or one Amoxicillin 875mg + Clavulanic acid 125mg Tablet twice daily)	One 625mg tablet twice daily. The Amoxicillin 875mg + Clavulanic acid 125mg Tablet should not be administered	Not more than one 625mg tablet every 24 hours.

Dosage in hepatic impairment:
Dose with caution: monitor hepatic function at regular intervals.

Administration:
Tablets should be swallowed whole without chewing. If required, tablets may be broken in half and swallowed without chewing.
To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption Cledomox is optimized when taken at the start of a meal.

Treatment should not be extended beyond 14 days without review.

Contraindications:
Hypersensitivity to the active substances, to any of the penicillins or to any of the excipients.
History of a severe immediate hypersensitivity reaction (e.g. anaphylaxis) to another beta-lactam agent (e.g. a cephalosporin, carbapenem or monobactam).
History of jaundice/hepatic impairment due to amoxicillin/clavulanic acid

Warning and precautions:
Before initiating therapy with amoxicillin/clavulanic acid, careful enquiry should be made concerning previous hypersensitivity reactions to penicillin, cephalosporin or other beta-lactam agents.

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 Cledomox 625, careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins, carbapenems or other beta-lactam agents. If an allergic reaction occurs, Cledomox 625 must be discontinued immediately and appropriate alternative therapy instituted.

Serious and occasionally fatal hypersensitivity reactions (including anaphylactoid and severe cutaneous adverse reactions) have been reported in patients on penicillin therapy.

In the case that an infection is proven to be due to an amoxicillin-susceptible organisms(s) then consideration should be given to switching from amoxicillin/clavulanic acid to amoxicillin in accordance with official guidance.

This presentation of Co-amoxiclav is not suitable for use when there is a high risk that the presumptive pathogens have reduced susceptibility or resistance to beta-lactam agents that is not mediated by beta-lactamases susceptible to inhibition by clavulanic acid.
This presentation should not be used to treat penicillin-resistant *S. pneumoniae*.

Convulsions may occur in patients with impaired renal function or in those receiving high doses.

Amoxicillin/clavulanic acid should be avoided if infectious mononucleosis is suspected since the occurrence of a morbilliform rash has been associated with this condition following the use of amoxicillin.

Concomitant use of allopurinol during treatment with amoxicillin can increase the likelihood of allergic skin reactions.

Prolonged use may occasionally result in overgrowth of non-susceptible organisms.

The occurrence at the treatment initiation of a feverish generalized erythema associated with pustula may be a symptom of acute generalized exanthemous pustulosis (AGEP). This reaction requires Co-amoxiclav discontinuation and contra-indicates any subsequent administration of amoxicillin.
Amoxicillin/clavulanic acid should be used with caution in patients with evidence of hepatic impairment.

Hepatic events have been reported predominantly in males and elderly patients and may be associated with prolonged treatment.
These events have been very rarely reported in children. In all populations, signs and symptoms usually occur during or shortly after treatment but in some cases may not become apparent until several weeks after treatment has ceased. These are usually reversible.
Hepatic events may be severe and, in extremely rare circumstances, deaths have been reported. These have almost always occurred in patients with serious underlying disease or taking concomitant medications known to have the potential for hepatic effects.

Antibiotic-associated colitis has been reported with nearly all antibacterial agents and may range in severity from mild to life threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea during or subsequent to the administration of any antibiotics. Should antibiotic-associated colitis occur, amoxicillin/clavulanic acid should immediately be discontinued, a physician be consulted and an appropriate therapy initiated. Anti-peristaltic medicinal products are contra-indicated in this situation.

Periodic assessment of organ system functions, including renal, hepatic and hematopoietic function is dvisable during prolonged therapy.

Prolongation of prothrombin time has been reported rarely in patients receiving amoxicillin/clavulanic acid. Appropriate monitoring should be undertaken when anticoagulants are prescribed concomitantly. Adjustments in the dose of oral anticoagulants may be necessary to maintain the desired level of anticoagulation.
In patients with renal impairment, the dose should be adjusted according to the degree of impairment.

In patients with reduced urine output, crystalluria has been observed very rarely, predominantly with parenteral therapy. During the administration of high doses of amoxicillin, it is advisable to maintain adequate fluid intake and urinary output in order to reduce the possibility of amoxicillin crystalluria. In patients with bladder catheters, a regular check of patency should be maintained.

During treatment with amoxicillin, enzymatic glucose oxidase methods should be used whenever testing for the presence of glucose in urine because false positive results may occur with non-enzymatic methods.

The presence of Clavulanic acid in Co-amoxiclav may cause a non-specific binding of IgG and albumin by red cell membranes leading to a false positive Coombs test.

There have been reports of positive test results using the Bio-Rad Laboratories Platelia Aspergillus EIA test in patients receiving amoxicillin/clavulanic acid who were subsequently found to be free of Aspergillus infection. Cross-reactions with non-Aspergillus polysaccharides and polyfuranoses with Bio-Rad Laboratories Platelia Aspergillus EIA test have been reported. Therefore, positive test results in patients receiving amoxicillin/clavulanic acid should be interpreted cautiously and confirmed by other diagnostic methods.

Drug Interactions:
Oral anticoagulants
Oral anticoagulants and penicillin antibiotics have been widely used in practice without reports of interaction. However, in the literature there are cases of increased international normalised ratio in patients maintained on acenocoumarol or warfarin and prescribed a course of amoxicillin. If co-administration is necessary, the prothrombin time or international normalised ratio should be carefully monitored with the addition or withdrawal of amoxicillin. Moreover, adjustments in the dose of oral anticoagulants may be necessary.

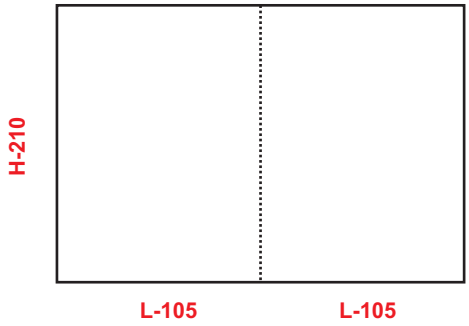
Methotrexate
Penicillins may reduce the excretion of methotrexate causing a potential increase in toxicity.

Probenecid
Concomitant use of probenecid is not recommended. Probenecid decreases the renal tubular secretion of amoxicillin. Concomitant use of probenecid may result in increased and prolonged blood levels of amoxicillin but not of clavulanic acid.

PREGNANCY & LACTATION

Pregnancy
Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. Limited data on the use of amoxicillin/clavulanic acid during pregnancy in humans do not indicate an increased risk of congenital malformations. In a single study in women with preterm, premature rupture of the foetal membrane it was reported that prophylactic treatment with amoxicillin/clavulanic acid may be associated with an increased risk of necrotising enterocolitis in neonates. Use should be avoided during pregnancy, unless considered essential by the physician.

NORMAL



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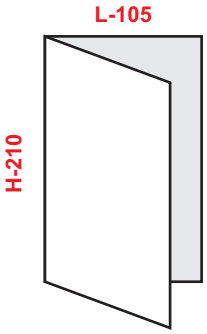

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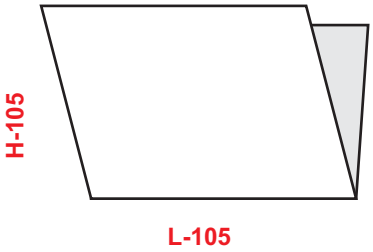

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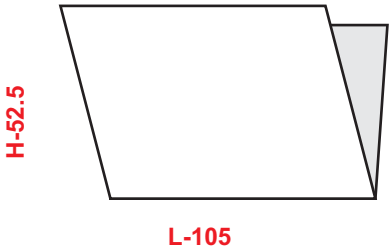

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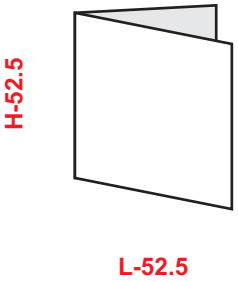

MEDOPHARM | Editorial : | | | Version :

Brand Name: **CLEDOMOX 625 mg TABLET**	*Client:* **MALAYSIA REGN. (Zulat Pharma)**	*Date:* **03-10-2025**
		Item Code: **PENC0730/05**
Generic Name: **CO-AMOXICLAV TABLETS BP**	*Type of Material:* **LITERATURE (Front & Back)**	*Software:* **CDR 24**
		Language: **ENGLISH**
Size: **H-210mm x L-210mm**		*Packing:*
Colors: **BLACK**		
Spec.: **70 gsm. / Maplitho**		
Remarks : **PHARMACODE : xxxx**	**FOLDING SIZE : H-52.5mm x L-52.5mm (4 Folding)**	

Software Specification

- ☐ Item Code
- ☐ Pharma Code
- ☐ Specification
- ☐ No. of Language Text
- ☐ Color/Pantone Specification

Comments

Sign & Date

CAUTION TO THE PRINTER: Before processing, Please ensure that the "Artwork" received for printing is exactly in match with approved artwork (CDR & PDF). In Case of any consequence with approved artwork (Font/Designs/Specification/Size) Please inform to artwork Department for further action. Do not make any change to the artwork without written instruction from artwork Department.

Artwork Dept.	Regulatory Affairs	Corporate QA	Quality Control	Production	Quality Assurance
☐ Item Code/Artwork Code	☐ Product and Specification	☐ Pharmacopeial status	☐ Product and Specification	☐ Dimensions	☐ Product and Specification
☐ Pharmacopeial status	☐ Pharmacopeial status	☐ Storage Condition	☐ Pharmacopeial status	☐ Change Parts	☐ Pharmacopeial status
☐ Specification	☐ Storage Condition	☐ Product License	☐ Storage Condition	☐ Over Printing Area	☐ Pharma Code Value
☐ Storage Condition	☐ Product License	☐ Different Language Text	☐ Product License	☐ Other Printing / Sticker fixing space	☐ Storage Condition
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☐ Product Registration No.	☐ Product Registration No.	☐ Item Code/Artwork Code	☐ Text match with other PM Components	☐ HDPE Container Volume	☐ Item Code/Artwork Code
☐ Proof Reading	☐ Company Details	☐ Text match with other PM Components			☐ Text match with other PM Components
☐ Color/Pantone Specification	☐ Text match with other PM Components				
☐ Text match with other PM Components					
Comments	Comments	Comments	Comments	Comments	Comments
Sign & Date	Sign & Date	Sign & Date	Sign & Date	Sign & Date	Sign & Date