

# CLEDOMOX 625mg TABLET

Amoxicillin/Clavulanic Acid (500mg/125mg)

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## What Cleodomox 625mg Tablet is used for

Cleodomox 625mg Tablet is used for the treatment of Upper respiratory tract infections - Lower respiratory tract infections - Genito-urinary tract and abdominal infections - Skin and soft tissue infections - Bone and joint infections - Dental infections - Other infections

## How Cleodomox 625mg Tablet works

Cleodomox 625mg Tablet is an antibiotic and works by killing bacteria that cause infections. It contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid.

## Before you use Cleodomox 625mg Tablet

### - When you must not use it

Do not take Cleodomox 625mg Tablet if:

- If you are having history of Allergic reactions to any penicillin, *beta-lactamase inhibitors* or *other beta-lactam antibiotics*. Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty in breathing and swelling of the face or tongue.
- If you are patients with previous history of amoxicillin with Clavulanate or penicillin associated jaundice/liver dysfunction.
- Please consult your doctor before start to use Cleodomox 625mg Tablet if you are pregnant, plan to become pregnant, breast-feeding or

intend to breast-feed. Your doctor will have weighed the risks of you taking Cleodomox 625mg Tablet against the benefits they expect it will have for you.

### - Before you start to use it

Tell your doctor if:

- If you have liver problem/cholestatic jaundice.
- If you have moderate or severe kidney impairment.
- If you are hypersensitive to penicillin.
- If you are having medical problems such as stomach and intestinal disease such as pseudomembranous colitis.
- If you have glandular fever (*mononucleosis*)
- If you are not passing urine regularly (crystalluria).

### - Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Cleodomox 625mg Tablet:

- *Probenecid* for gout.
- *Allopurinol* for gout.
- Anticoagulant agent, blood thinning agent.
- *Methotrexate*

## How to use Cleodomox 625mg Tablet

### - How much to use

"Cleodomox 625mg tablet is available in only one strength of 625mg (Amoxicillin 500mg + Clavulanic acid 125mg). Cleodomox 625mg Tablet 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 Cleodomox 625mg tablet twice daily.
- Severe infections: One Amoxicillin 875mg + Clavulanic acid 125mg Tablet twice daily.

Dosage in dental infections (e.g. dental abscess)

- Adults and children over 12 years: one Cleodomox 625mg tablet twice daily for 5 days
- Cleodomox 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); No change in dosage ( i.e. either one 625mg tablet twice daily or one Amoxicillin 875mg + Clavulanic acid 125mg Tablet twice daily)
- Moderate impairment (creatinine clearance 10-30 ml/min); One 625mg tablet twice daily. The Amoxicillin 875mg + Clavulanic acid 125mg Tablet should not be administered
- Severe impairment creatinine clearance, 10ml/min); Not more than one 625mg tablet every 24 hours.

Dosage in hepatic impairment:

- Dose with caution: monitor hepatic function at regular intervals.

Treatment should not be extended beyond 14 days without review.

Not recommended for children of 12 years and below.

### - When to use it

Your doctor will decide when it is appropriate for you to use Cleodomox 625mg Tablet according to the type of condition you have.

### - How long to use it

Continue taking Cleodomox 625mg Tablet for as long as doctor recommends.

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Do not stop taking medication, even if you feel better after a few days, unless advised by your doctor. Your infection may not clear completely if you stop taking your medicine too soon.

**- If you forget to use it**

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose.

Do not take a double dose to make up for the missed dose.

**If you use too much (overdose)**

- Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.
- Gastrointestinal symptoms and disturbance of the fluid and electrolyte balances may be evident. Crystalluria (Crystals in the urine), 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.

**While you are using it**

**- Things you must do**

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Cledomox 625mgTablet.
- Tell your doctor immediately if you become pregnant while talking this medication.

- If you get severe diarrhoea tell your doctor or pharmacist immediately.

**- Things you must not do**

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Cledomox 625mgTablet to anyone else, even if they have the same symptoms or condition as you.

**- Things to be careful of**

- Avoid prolonged use of this product.
- Adequate fluid intake and urinary output should be maintained during administration of high doses amoxicillin/clavulanate.
- Pregnancy and lactation.
- Be careful when driving or operating machinery until you know how Cledomox 625mgTablet affects you.

**Side Effects**

Like all medicines, Cledomox 625mgTablet can cause side effects although not everybody gets them. You are advised to consult doctor/pharmacist for further information.

The following common side effects have been reported:

- Diarrhoea
- Nausea
- Vomiting
- Candidiasis (fungal infection that can affect skin, genitals, throat and mouth).

Stop taking Cledomox 625mg and contact your doctor immediately if you experience any of the following:

- Serious allergic reactions such as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). DRESS appears initially as flu-like symptoms with a rash on the face and then with an extended rash, high temperature and enlarged lymph nodes.

Cledomox 625 may cause severe allergy and serious skin reactions.

**Stop using Cledomox 625 and seek medical assistance immediately if you experience any of the following**

**symptoms: Skin reddening, blisters,**

**rash, fever, sore throat or eye irritation.**

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) [Public-> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]”.

**Storage and disposal of Cledomox 625mgTablet**

**Storage**

Keep out of the reach and sight of children.  
Store below 30°C. Protect from light and moisture.

**Disposal**

Do not use Cledomox 625mgTablet after the expiry date which is stated on the carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

These measures will help to protect the environment.

**Product description**

**What it looks like**

Cledomox 625mg Tablet is white oval-shaped film-coated tablets. They are packaged in a plain Alu-Alu foil and Printed aluminium blister foil.

Such 10 blisters are packed in printed carton with a package insert.

**Ingredients**

**Active Ingredient:**

Amoxicillin Trihydrate, Potassium Clavulanate.

**Inactive Ingredients:**

Microcrystalline Cellulose, Magnesium stearate, Sodium Starch Glycolate, Colloidal Silicon Dioxide, Ethyl Cellulose, Propylene Glycol, Hydroxypropyl Methylcellulose (HPMC) compound mix, Dimethicone. Opaspray KIR 7000,

# CLEDOMOX 625mg TABLET

Amoxicillin/Clavulanic Acid (500mg/125mg)

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Methylene  
Chloride/Dichloromethane, Isopropyl  
Alcohol

MAL Number

MAL17085040AZ

**Manufacturer:**

Medopharm Private Limited,  
No 50, Kayarmabedu Village,  
Guduvanchery, TamilNadu – 603 202,  
INDIA.

**Product registration holder:**

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

**Date of revision**

23/02/2026

**Serial Number**

NPRA(R2/2)260219/00020