

CAVUMOX 625 MG TABLET

Amoxicillin / Clavulanic Acid (500 mg / 125 mg)

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1. What CAVUMOX is used for.

Contains 500 mg amoxicillin and 125 mg clavulanic acid per tablet.

It is an antibiotic agent with a notably broad spectrum of activity against the commonly occurring bacterial pathogens in general practice and hospital. The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotics. CAVUMOX should be used in accordance with local official antibiotic-prescribing guidelines and local susceptibility data. CAVUMOX oral presentations 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, pyelonephritis)
- Skin and soft tissue infections (e.g., boils, abscesses, cellulitis, wound infections)
- Bone and joint infections (e.g., osteomyelitis)
- Dental infections (e.g., dentoalveolar abscess)

- Other infections (e.g., septic abortion, puerperal sepsis, intra-abdominal sepsis)

Susceptibility to CAVUMOX will vary with geography and time. Local susceptibility data should be consulted where available, and microbiological sampling and susceptibility testing performed where necessary.

2. How CAVUMOX works

The beta-lactamase inhibitory action of clavulanate extends the spectrum of amoxicillin to embrace a wider range of organisms, including many resistant to other beta-lactam antibiotics.

3. Before you use CAVUMOX

When you must not use it

Do not use **CAVUMOX** if:

You/your child are allergic to amoxicillin and clavulanic acid or any other ingredients in this product.

Before you start to use it

Talk to your doctor or pharmacist before taking **CAVUMOX** if you/your child have or have had any allergic reaction.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket, or health food shop.

4. How to use CAVUMOX

How much and when to use

Dosage depends on the age, renal function of the patient and the severity of the infection.

To minimize potential gastrointestinal intolerance, administer at the start of a meal. The absorption of CAVUMOX is optimized when taken at the start of a meal.

Treatment should not be extended beyond 14 days without review.

Therapy can be started parenterally and continued with an oral preparation.

Tablets should be swallowed whole without chewing. If required, tablets may be broken in half and swallowed without chewing.

CAVUMOX tablets are not recommended in children of 12 years and under.

Adults and Children over 12 years

Mild to moderate infections: One CAVUMOX 625 mg tablet every 12 hours

Severe infections: One CAVUMOX 1 g tablet every 12 hours

Renal Impairment

No adjustment in dose is required in patient with creatinine clearance greater (CrCl) than 30 mL/min. CAVUMOX 1 g tablet should only be used in patient with a CrCl rate of more than 30 mL/min.

CrCl 10 – 30 mL/mlm	One CAVUMOX 625 mg tablet every 12 hours
CrCl < 10 mL/min	One CAVUMOX 625 mg tablet every 24 hours
Haemodialysis	One CAVUMOX 625 mg tablet every 24 hours, plus a further one tablet during dialysis, to be repeated at the end of dialysis (as serum concentrations of both amoxicillin and clavulanic acid are decreased).

Hepatic Impairment

Dose with caution, monitor hepatic function at regular intervals.

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How long to use it

Continue taking this medicine for as long as prescribed by your doctor.

If you forget to use it

Continue to use as stated on the label

If you use too much (overdose)

Immediately inform your doctor or go to the Emergency Department of your nearest hospital if you suspect that you or anyone else may have taken too much of this medicine. Do this even if you are not experiencing signs of discomfort or poisoning as you may need urgent medical attention.

5. While you are using it

Things you must do

- Follow these instructions unless your doctor gave you different advice.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not give this medicine to anyone else, even if they have similar symptoms as you.
- As with all medicines, use should be avoided in pregnancy, especially during the first trimester, unless considered essential by the physician.

Things to be careful of

- Always take or give this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
- The medicinal product 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 detrimental effects for the infant.

6. Side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. The following side effects may be occurred:

Dizziness, headache, diarrhoea, nausea, vomiting, indigestion, skin rash and associated to this.

Stop taking CAVUMOX 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.

You may report any side effect or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

7. Storage and Disposal

Store in a tight container and in dry place below 30°C.

8. Product Description

What it looks like

White, oblong, biconvex film coated tablet. 5 blister strips x 3 film-coated tablets per unit box

Ingredients

Active ingredient:

CAVUMOX 625mg tablet contains 500 mg amoxicillin (as amoxicillin trihydrate) and 125 mg clavulanic acid (as potassium clavulanate) per tablet.

MAL number: MAL20032432AZ

9. Manufacturer

Siam Bheasach Co., Ltd.,

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Vibhavadi-Rangsit Road, Chomphon,
Chatuchak, Bangkok 10900 and

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10. Product Registration Holder

SPG Pharma (Malaysia) Sdn. Bhd.,
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11. Date of revision

29 Nov 2022

12. Serial Number

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