

PATIENT INFORMATION LEAFLET

1. NAME OF THE PRODUCT

Clamox Film-Coated Tablets 1g

2. DESCRIPTION OF PRODUCT

White to off white capsule shaped, biconvex tablets de bossed with "I 07" on one side and plain on the other side

3. WHAT IS IN THE MEDICINE?

Amoxicillin and clavulanic acid is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called “penicillins” that can sometimes be stopped from working (made inactive). The other active component (clavulanic acid) stops this from happening.

4. STRENGTH OF THE MEDICINE

875/125 mg

5. WHAT IS THIS MEDICINE USED FOR?

Amoxicillin and clavulanic acid is used in adults and children to treat the following infections:

- Middle ear and sinus infections
- Respiratory tract infections
- Urinary tract infections
- Skin and soft tissue infections including dental infections
- Bone and joint infections.

6. HOW MUCH AND HOW OFTEN SHOULD YOU USE THIS MEDICINE?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years

Usual dose – 1 tablet two times a day

Patients with kidney and liver problems

- If you have kidney problems the dose might be changed. A different strength or a different medicine may be chosen by your doctor.
- If you have liver problems you may have more frequent blood tests to check how your liver is working.

How to take Amoxicillin and clavulanic acid

- Swallow the tablets whole with a glass of water with a meal.
- Do not take Amoxicillin and clavulanic acid for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

7. WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

Do not take Amoxicillin and clavulanic acid:

- If you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine
- If you have ever had a severe allergic reaction to any other antibiotic. This can include a skin rash or swelling of the face or throat.
- If you have ever had liver problems or jaundice (yellowing of the skin) when taking amoxicillin/clavulanic acid.

Do not take Amoxicillin and clavulanic acid if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin and clavulanic acid.

8. UNDESIRABLE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects below may happen with this medicine.

Conditions you need to look out for

Allergic reactions:

- Skin rash
- Inflammation of blood vessels (Vasculitis) which may be visible as red or purple raised spots on the skin, but can affect other parts of the body
- Fever, joint pain, swollen glands in the neck, armpit or groin
- Swelling, sometimes of the face or throat (angioedema), causing difficulty in breathing
- Collapse.

Contact a doctor immediately if you get any of these symptoms. Stop taking Amoxicillin and clavulanic acid.

Inflammation of large intestine

Inflammation of the large intestine, causing watery diarrhoea usually with blood and mucus, stomach pain and/or fever.

Contact your doctor as soon as possible for advice if you get these symptoms.

Very common side effects

These may affect more than 1 in 10 people

Diarrhoea (in adults).

Common side effects

- These may affect up to 1 in 10 people
- Thrush (candida - a yeast infection of the vagina, mouth or skin folds)

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CO-AMOXICLAV TABLETS 875 mg/125 mg



- Feeling sick (nausea), especially when taking high doses
- Vomiting
- Diarrhoea (in children).

Uncommon side effects

These may affect up to 1 in 100 people

- Skin rash, itching
- Raised itchy rash (hives)
- Indigestion
- Dizziness
- Headache.

Uncommon side effects that may show up in your blood tests:

- Increase in some substances (enzymes) produced by the liver.

Rare side effects

These may affect up to 1 in 1000 people

- skin rash, which may blister, and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge – erythema multiforme)

If you notice any of these symptoms contact a doctor urgently.

Rare side effects that may show up in your blood tests:

- Low number of cells involved in blood clotting
- Low number of white blood cells.

Cardiac disorders

Very rare Kounis syndrome

Frequency not known

Frequency cannot be estimated from the available data.

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- Serious skin reactions:
 - A widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form, causing extensive peeling of the skin (more than 30% of the body surface – toxic epidermal necrolysis)
 - Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
 - A red, scaly rash with bumps under the skin and blisters (exanthemous pustulosis).
- Flu-like symptoms with a rash, fever, swollen glands, and abnormal blood test results (including increased white blood cells (eosinophilia) and liver enzymes) (Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)).

Contact a doctor immediately if you get any of these symptoms.

- Inflammation of the liver (hepatitis)

- Jaundice, caused by increases in the blood of bilirubin (a substance produced in the liver) which may make your skin and whites of the eyes appear yellow
- Inflammation of tubes in the kidney
- Blood takes longer to clot
- Hyperactivity
- Convulsions (in people taking high doses of Amoxicillin and clavulanic acid or who have kidney problems)
- Black tongue which looks hairy

Side effects that may show up in your blood or urine tests:

- Severe reduction in the number of white blood cells
- Low number of red blood cells (haemolytic anaemia)
- Crystals in urine.

9. WHAT OTHER MEDICINE OR FOOD SHOULD BE AVOIDED WHILST TAKING THIS MEDICINE?

Tell your doctor or pharmacist if you are using or have recently used or might use any other medicines.

If you are taking allopurinol (used for gout) with Amoxicillin and clavulanic acid, it may be more likely that you will have an allergic skin reaction.

If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Amoxicillin and clavulanic acid.

If medicines to help stop blood clots (such as warfarin) are taken with Amoxicillin and clavulanic acid then extra blood tests may be needed. Amoxicillin and clavulanic acid can affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

10. WHAT SHOULD YOU DO IF YOU MISS A DOSE?

If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose.

11. HOW SHOULD YOU KEEP THIS MEDICINE?

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Store in the original package in order to protect from moisture.

Do not use if the tablets are chipped or damaged.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

12. SIGNS & SYMPTOMS OF OVER DOSAGE

Symptoms and signs

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.

Treatment

Gastrointestinal symptoms may be treated symptomatically, with attention to the water/electrolyte balance.

Amoxicillin/clavulanic acid can be removed from the circulation by haemodialysis.

13. WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you take too much Amoxicillin and clavulanic acid, signs might include an upset stomach (feeling sick, being sick or diarrhoea) or convulsions. Talk to your doctor as soon as possible. Take the medicine carton or bottle to show the doctor.

14. NAME/LOGO OF MANUFACTURER/IMPORTER/MARKETING

Manufacturer

MICRO LABS LIMITED

Plot No. 16 & 24, Veerasandra Industrial Area,
Anekal Taluk, Bengaluru-560 100
INDIA.

Marketing Authorization Holder

Gold plus Universal Pte Ltd
21 Serangoon North Ave 5, #07-01/02
Singapore 554864

15. CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE?

Talk to your doctor or pharmacist before taking Amoxicillin and clavulanic acid if you:

- Have glandular fever
- Are being treated for liver or kidney problems
- Are not passing water regularly

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking Amoxicillin and clavulanic acid.

In some cases, your doctor may investigate the type of bacteria that is causing your infection. Depending on the results, you may be given a different strength of Amoxicillin and clavulanic acid or a different medicine.

Conditions you need to look out for Amoxicillin and clavulanic acid can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits) and inflammation of the large intestine. You must look out for certain symptoms while you are taking Amoxicillin and clavulanic acid, to reduce the risk of any problems. See 'Conditions you need to look out for' in Section 4.

Blood and urine tests

If you are having blood tests (such as red blood cell status tests or liver function tests) or urine tests (for glucose), let the doctor or nurse know that you are taking Amoxicillin and clavulanic acid. This is because Amoxicillin and clavulanic acid can affect the results of these types of tests.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

16. WHEN SHOULD YOU CONSULT YOUR DOCTOR?

Keep taking Amoxicillin and clavulanic acid until the treatment is finished, even if you feel better. You need every dose to help fight the infection. If some bacteria survive they can cause the infection to come back.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

17. DATE OF REVISION OF PIL

December 2022