



Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you (or for your child) only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4

WHAT IS IN THIS LEAFLET

1. What BACTOCLAV is and what it is used for
2. What you need to know before you take BACTOCLAV
3. How to take BACTOCLAV
4. Possible side effects
5. How to store BACTOCLAV
6. Contents of the pack and other information

1. WHAT BACTOCLAV IS AND WHAT IT IS USED FOR

It 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.

Amoxicillin and Potassium clavulanate 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE BACTOCLAV

Do not take Amoxicillin and Potassium clavulanate:

- if you are allergic to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (listed in section 6)
- if you have ever had a severe allergic (hypersensitive) reaction to any other antibiotic. This can include a skin rash or swelling of the face or neck
- If you have ever had liver problems or jaundice (yellowing of the skin) when taking an antibiotic.
- Do not take Amoxicillin and Potassium clavulanate if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Amoxicillin and Potassium clavulanate.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Amoxicillin and Potassium clavulanate 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 apply to you, talk to your doctor or pharmacist before taking Amoxicillin and Potassium clavulanate.

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 Potassium clavulanate or a different medicine.

Conditions you need to look out for

Amoxicillin and Potassium clavulanate 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 Potassium clavulanate, 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 Potassium clavulanate. This is because Amoxicillin and Potassium clavulanate can affect the results of these type of tests.

Other medicines and Amoxicillin and Potassium clavulanate

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

- If you are taking allopurinol (used for gout) with Amoxicillin and Potassium clavulanate, 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 Potassium clavulanate.
- If medicines to help stop blood clots (such as warfarin) are taken with Amoxicillin and Potassium clavulanate then extra blood tests may be needed.
- Amoxicillin and Potassium clavulanate can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- Amoxicillin and Potassium clavulanate may affect how mycophenolate mofetil (a medicine used to prevent the rejection of transplanted organs) works.

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.

Driving and using machines

Amoxicillin and Potassium clavulanate can have side effects and the symptoms may make you unfit to drive. Do not drive or operate machinery unless you are feeling well.

3. HOW TO TAKE BACTOCLAV

Always take Amoxicillin and Potassium clavulanate exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children weighing 40 kg and over

The usual dose is:

- 1 tablet three times a day

Children weighing less than 40 kg

Children aged 6 years or less should preferably be treated with Amoxicillin and Potassium clavulanate oral suspension or sachets.

Ask your doctor or pharmacist for advice when giving Amoxicillin and Potassium clavulanate tablets to children weighing less than 40 kg. The tablets are not suitable for children weighing less than 25 kg.

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 see how your liver is working.

How to take Amoxicillin and Potassium clavulanate

- Swallow the tablets whole with a glass of water at the start of a meal or slightly before. Tablets can be broken along the score line to make them easier to swallow. You must take both pieces of the tablet at the same time.
- Space the doses evenly during the day, at least 4 hours apart. Do not take 2 doses in 1 hour.
- Do not take Amoxicillin and Potassium clavulanate for more than 2 weeks. If you still feel unwell you should go back to see the doctor.

If you take more Amoxicillin and Potassium clavulanate than you should

If you have too much Amoxicillin and Potassium clavulanate, 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.

If you forget to take Amoxicillin and Potassium clavulanate

- If you forget to take a dose, take it as soon as you remember.
- You should not take the next dose too soon, but wait about 4 hours before taking the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Amoxicillin and Potassium clavulanate

Keep taking Amoxicillin and Potassium clavulanate 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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 mouth (*angioedema*), causing difficulty in breathing collapse.
- Contact a doctor immediately if you get any of these symptoms. Stop taking Amoxicillin and Potassium clavulanate.

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)
- Feeling sick (nausea), especially when taking high doses
- If affected take Amoxicillin and Potassium clavulanate before food
- 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.

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*).

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 Potassium clavulanate 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.

5. HOW TO STORE BACTOCLAV

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 25°C.

Tablets supplied in pouches should be used within 30 days of opening the pouch.

Store in the original pack 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.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Bactoclav contains

Active ingredients: Amoxicillin and Clavulanic acid

The other ingredients are: Microcrystalline Cellulose, Colloidal Silicon Dioxide, Sodium Starch Glycolate, Magnesium Stearate, Tab coat, TC-1709 MB White.

What BACTOCLAV looks like and contents of the pack

White or off white, Capsule shaped film coated tablets with break line on one side and plain on other side.

Strip pack of 6's and 10's

Alu-Alu blister pack of 10's

Manufacturer

MICRO LABS LIMITED

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Bangalore -560 100

Marketing Authorisation Holder

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INDIA

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