



PACKAGE LEAFLET

AMOKLAVIN-BID 1000 mg Film Coated Tablets

Taken by mouth.

Active substance: Each tablet contains amoxicillin trihydrate (produced from bovine, sheep or goat milk) equal to 875 mg amoxicillin and potassium clavulanate equal to 125 mg clavulanic acid.

Excipients: Sodium starch glycolate, microcrystalline cellulose, silica colloidal hydrate (syloid AL-1-FP), colloidal silicon dioxide, magnesium stearate, Opadry O4-F-28791 white (hydroxypropyl methylcellulose 15 Cp, titanium dioxide, polyethylene glycol 4000, polyethylene glycol 6000).

Read all of this PACKAGE 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. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this drug, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take this medicine in either **higher** or **lower** dose other than recommended to you.*

In this leaflet:

- 1. What AMOKLAVIN-BID is and what it is used for**
- 2. What you need to know before you take AMOKLAVIN-BID**
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1. WHAT AMOKLAVIN-BID IS AND WHAT IT IS USED FOR

AMOKLAVIN-BID is a broad-spectrum antibacterial medicine and works by killing bacteria that cause infections. It contains two different active substances, amoxicillin and clavulanic acid. Amoxicillin belongs to a group of medicines called 'penicillins' that can sometimes be inactivated (stopped from working) and clavulanic acid prevents the inactivation of amoxicillin.

AMOKLAVIN-BID 1000 mg film-coated tablet is available in blister packs containing 10, 14 or 20 white, odorless, slightly convex, oblong, homogenous, film-coated tablets, scored on one side and imprinted DEVA on the other. Amoxicillin trihydrate is produced from bovine, sheep or goat milk.

AMOKLAVIN-BID is for the short-term treatment of following infections in adults and children caused by susceptible bacteria:

- Upper respiratory tract infections like sinus inflammation caused by bacteria (diagnosed with proper diagnosis), acute otitis media, and recurrent tonsillitis.
- Lower respiratory tract infections like acute exacerbations of chronic bronchitis, (diagnosed with proper diagnosis), community-acquired pneumonia (lung inflammation that occurs during a person's daily life).
- Urinary tract infections like urethra (bladder) inflammation, bacterial infections of kidneys
- Skin and soft tissue infections such as cellulitis (inflammation of the subcutaneous layer and fatty tissue) and animal bites
- Dental infections such as severe dental abscesses with widespread cellulitis (inflammation of the subcutaneous layer and fatty tissue).
- Bone and joint infections especially inflammation of bones (osteomyelitis).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AMOKLAVIN-BID

DO NOT take AMOKLAVIN-BID

- If you are allergic to amoxicillin, clavulanic acid, penicillin or any ingredients of this medicine (see the list of the excipients at the beginning of this package leaflet),
- If you have ever had a serious allergic reaction (hypersensitivity) to any other antibiotic: This reaction may include skin rash or swelling of the face or throat,
- If you have ever had jaundice or liver problems while using antibiotics,

If any of the above applies to you, do not use AMOKLAVIN-BID.

If you are not sure, consult your doctor or pharmacist before using AMOKLAVIN-BID.

TAKE SPECIAL CARE with AMOKLAVIN-BID

- If you are being treated for liver or kidney problems.
- If your urine output is not regular
- If you have glandular fever (a type of viral infection)
- If you suspect infectious mononucleosis (an infective disease), (occurrence of a morbilliform rash following the use of amoxicillin can be associated with infectious mononucleosis)
- Use AMOKLAVIN-BID as long as recommended by your doctor. Long-term use results in overgrowth of non-susceptible organisms (i.e. fungi).
- Prolongation of bleeding and prothrombin time has been reported in some patients receiving AMOKLAVIN-BID. Appropriate monitoring should be undertaken if you would use it concomitantly with anticoagulants.
- In patients with reduced urine output, crystalluria (passing stones) has been observed. Adequate fluid intake should be maintained to reduce this.
- If antibiotic-induced inflammation of large intestine (colitis) is observed, AMOKLAVIN-BID treatment should be discontinued immediately, and if this situation occurs in you or your child, it should be evaluated by a doctor and appropriate treatment should be started. In this case, do not use or give to your child anti-peristaltic drugs that prevent bowel movements.

If these warnings apply to you, even for any time in the past, please consult your doctor.

In some cases, your doctor may investigate the type of bacteria causing the infection. Depending on the results, a different dose of AMOKLAVIN-BID or a different medicine may be given.

Situations you should pay attention to:

It may be a symptom of acute generalized exanthematous pustulosis (AGEP - a clinical condition characterized by a skin blister (pustule) containing an inflammatory fluid on widespread reddened skin, accompanied by high fever, which develops rapidly and in a short time, often after drug use). This reaction requires discontinuation of AMOKLAVIN-BID and amoxicillin should not be used subsequently. AMOKLAVIN-BID may worsen some pre-existing conditions or cause serious side effects. These include allergic reactions, convulsions (seizures), and inflammation of the colon. To reduce the risk of any problems occurring, you should be aware of certain symptoms while taking AMOKLAVIN-BID. See **section 4** “*Situations you should pay attention to*”.

Blood and urine test

If you are having blood tests (red blood cell status tests or liver function tests) or urine tests (for glucose), let your doctor know that you are taking AMOKLAVIN-BID. This is because AMOKLAVIN-BID can affect the results of these types of tests.

Taking AMOKLAVIN-BID with food and drink

AMOKLAVIN-BID should be taken with meals to minimize the risk of gastro-intestinal disorders.



Pregnancy

Consult your doctor or pharmacist before taking this medicine.

Unless deemed necessary by your doctor, do not use during pregnancy and especially during the first three months of pregnancy.

Concomitant use of AMOKLAVIN-BID and birth control pills may reduce the effectiveness of birth control pills. Therefore, it may be necessary to use an additional birth control method while using AMOKLAVIN-BID.

If you realize you are pregnant during treatment, immediately see your doctor or pharmacist.

Breastfeeding

Consult your doctor or pharmacist before taking this medicine.

Both drug substances of AMOKLAVIN-BID are excreted into breast milk. Consequently, diarrhea and fungus infection of the mucous membranes are possible in the breast-fed infant, so that breastfeeding might have to be discontinued. Your doctor will decide if amoxicillin/clavulanic acid is the correct choice for you during breastfeeding or not.

Driving and using machines

AMOKLAVIN-BID may induce undesirable effects such as allergic reactions, dizziness and convulsion (seizure; abnormal muscle contractions, which may be prolonged or intermittent, resulting from abnormal activity of brain cells). Do not drive and use machine until you feel well.

Important information about some of the ingredients of AMOKLAVIN-BID

This product contains less than 1 mmol sodium (23 mg) per tablet; i.e. essentially sodium-free”.

Taking other medicines

- If you are taking allopurinol (used to treat gout) with AMOKLAVIN-BID, it may be more likely that you will have an allergic skin reaction.
- If you are taking probenecid (used to treat gout), your doctor may decide to adjust your dose of AMOKLAVIN-BID.
- If you are on drugs to help stop blood clots (such as warfarin), you may need extra blood tests.
- AMOKLAVIN-BID can affect how methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- AMOKLAVIN-BID may affect how mycophenolate mofetil (a medicine used in organ transplantation) works.
- Concomitant use of AMOKLAVIN-BID with oral contraceptives may reduce the efficacy of oral contraceptives.

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

3. HOW TO TAKE AMOKLAVIN-BID

Instructions for proper use and dose/frequency of administration

Always take AMOKLAVIN-BID exactly as your doctor or pharmacist tells you. If you are not sure, ask your doctor or pharmacist.

For adults and ≥ 40 kg children

- 1 tablet twice a day as standard dose (for all indications),
- It is recommended to take 1 tablet 3 times a day as a high dose (especially for otitis media, lower respiratory tract infections and urinary tract infections).

For children weighing less than 40 kg:

Children under 6 years should preferably be treated with AMOKLAVIN-BID oral suspensions. Your doctor or pharmacist should be consulted before using AMOKLAVIN-BID tablets for children weighing less than 40 kg. Tablet forms are not suitable for children under 25 kg.

For patients with kidney or liver problems:

- If you have kidney problems, the dose of your medicine may be changed. A different dose or medication may be prescribed by your doctor.
- If you have liver problems, you may have more frequent blood tests to check the condition of your liver.

Route and method of administration

Take with meals.

Tablets should be swallowed as a whole without chewing. If required, due to difficulty swallowing, tablets can be broken into two parts and swallowed consecutively without chewing.

Take the doses evenly throughout the day, at least 4 hours apart. Do not take two doses in an hour. Do not use AMOKLAVIN-BID for longer than 2 weeks. If you still feel unwell, see your doctor.

Different age groups

Use in children: Children can be treated with tablets or suspensions of AMOKLAVIN-BID. Children under 25 kg should not be treated with AMOKLAVIN-BID tablets. Children aged 6 years and under or weighing less than 25 kg should preferably be treated with suspension forms of AMOKLAVIN-BID.

Use in elderly: Dose adjustment is not considered necessary.

Special conditions of use

Kidney/Liver Failure: If you have kidney or liver failure, your dose should be adjusted carefully and reduced, if required.

Hemodialysis (blood cleaning process): If you are undergoing hemodialysis, your dose should be adjusted carefully.

If you have the impression that the effect of AMOKLAVIN-BID is too strong or too weak, talk to your doctor or pharmacist.

If you take more AMOKLAVIN-BID than you should

If you take too much AMOKLAVIN-BID, symptoms may include stomach upset (feeling sick, being sick or diarrhea) or convulsions (seizures).

If you use more AMOKLAVIN-BID than you should, inform your doctor as soon as possible. You can take the box of medicine with you to show it to your doctor.

If you have taken too much AMOKLAVIN-BID, talk to your doctor or pharmacist.

If you forget to take AMOKLAVIN-BID

If you forget to take a dose, take it as soon as you remember. Do not take the next dose too soon; wait about four hours to take the next dose.

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



If you stop taking AMOKLAVIN-BID

You should take AMOKLAVIN-BID as long as recommended by your doctor. Keep taking AMOKLAVIN-BID for the full time of treatment, even if you feel better. Each dose taken is needed to help fight infection. If some of the bacteria survive, they can cause the infection to relapse. If you have additional questions about the use of this medication, consult your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in people with sensitivity to ingredients of AMOKLAVIN-BID. The following side effects may occur with the use of this medicine.

If you experience any of the following side effects, stop taking AMOKLAVIN-BID and inform your doctor or go to the emergency department of the nearest hospital STRAIGHT AWAY:

Situations you should pay attention to

Allergic reactions:

- Skin rash,
- Inflammation of blood vessels (vasculitis); visible as red or purple raised spots on the skin, but can also affect other parts of the body,
- Fever, joint pain, swelling of the neck, armpit or groin glands,
- Sometimes swelling of the face or throat (angioedema), swelling that makes breathing difficult,
- Collapse (a severe collapse caused by the expansion of peripheral vessels and collection of blood there, sudden cessation of all forces in the body),
- Chest pain associated with allergic reactions (Kounis syndrome), which may be a symptom of an allergy-triggered heart attack,

If you get any of these symptoms, **see a doctor immediately, stop taking AMOKLAVIN-BID.**

Inflammation of the large intestine

Inflammation of the large intestine causing watery diarrhea, stomach pain, and/or fever, often accompanied by blood and slimy tissue (mucus).

Drug-induced enterocolitis syndrome (DIES)

DIES has been reported particularly in children receiving amoxicillin/clavulanic acid. It is a specific type of allergic reaction with main symptom of recurrent vomiting (1 to 4 hours after drug use). Other symptoms are abdominal pain, lethargy (constant sleep), diarrhea and low blood pressure.

Acute inflammation of the pancreas (acute pancreatitis)

If you have severe and persistent pain in the stomach area, this may be a sign of acute pancreatitis.

If you experience these symptoms, **contact your doctor as soon as possible** to get advice.

Side effects are described as shown in the following categories:

Very common : may be seen in at least 1 in 10 patients.

Common : may be seen in less than 1 in 10 patients, but in more than 1 in 100 patients.

Uncommon : may be seen in less than 1 in 100 patients, but in more than 1 in 1,000 patients.

Rare : may be seen in less than 1 in 1,000 patients, but in more than 1 in 10,000 patients.

Very rare : may be seen in less than 1 in 10,000 patients.

Not known : cannot be estimated based on available data



Very common:

- Diarrhea (in adults)

Common:

- A type of fungal infection that affects the mucous membranes and skin (mucocutaneous candidiasis).
- Feeling sick (nausea), especially when taken in high doses.

If this effect is present, AMOKLAVIN-BID should be taken with food.

- Vomiting
- Diarrhea (in children)

Uncommon:

- Skin rash
- Itching
- Hives
- Dizziness
- Headache
- Digestive difficulties

Uncommon side effects that may show in your blood tests:

- Increase in some substances (enzymes) produced by the liver (this side effect can be seen in blood tests)

Rare:

- Skin rash appears as raised and small marks (erythema multiforme, which is observed as a lighter area around the central dark spots and a dark ring at the border)

If you notice any of these symptoms, contact a doctor immediately.

- Reversible leukopenia (including neutropenia) and thrombocytopenia (decrease in the number of some blood cells).

Rare side effects may also be observed in blood tests:

- Decrease in the number of cells required for blood clotting
- Decrease in the number of white blood cells

Not known:

- Allergic reactions (see above)
- Inflammation of the large intestine (see above)
- Inflammation of the membranes surrounding the brain and spinal cord (aseptic meningitis)
- Serious skin reactions:
 - Widespread skin rash with blisters and peeling skin, especially around the mouth, nose, eyes and genital areas (Stevens-Johnson syndrome), and in more serious forms, intense peeling of the skin (over 30% of the body surface – toxic epidermal necrolysis)
 - Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
 - Red, scaly rash with blisters and blisters under the skin (exanthematous pustulosis).
 - Rash with flu-like symptoms, fever, swollen glands and abnormal blood test results (including increases in white blood cells (eosinophilia) and liver enzymes) (Drug reaction)

with eosinophilia and systemic symptoms (DRESS)).
- Overgrowth of non-susceptible microorganisms

If you experience any of these symptoms, contact a doctor immediately.

- Rash with crusting in the center or blisters arranged in a circle like a string of pearls (linear IgA disorder)
- Liver inflammation (hepatitis)
- Jaundice due to an increase in bilirubin (a substance produced by the liver) in the blood, which causes the skin and whites of your eyes to appear yellow
- Inflammation of the renal tubes (interstitial nephritis)
- Prolonged blood clotting
- Hyperactivity
- Convulsions (in people taking high doses of AMOKLAVIN-BID or having kidney problems)
- The color of the tongue is black

Side effects that may be seen in your blood or urine tests:

- Severe decrease in white blood cell count
- Low number of red blood cells (hemolytic anemia)
- Appearance of crystals in the urine (crystalluria (causing acute kidney damage))

If you notice any side effects not listed in this package leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE AMOKLAVIN-BID

Keep AMOKLAVIN-BID out of the reach and sight of children and in its original package.

Keep at room temperature below 25°C and in a dry place.

Use it in line with the expiry date.

Do not use AMOKLAVIN-BID after the expiry date, which is stated on the packaging.

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.

Marketing Authorization Holder:

DEVA Holding A.Ş.
Küçükçekmece – İSTANBUL / TÜRKİYE

Manufacturing Site:

DEVA Holding A.Ş.
Kapaklı - TEKİRDAĞ / TÜRKİYE

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