PACKAGE LEAFLET: INFORMATION FOR THE USER

AMOKLAVIN 1.2 g Powder for Solution for IV Injection/Infusion
Administered into vein.
Sterile

Active Substance: Each vial contains 1060.208 mg amoxicillin sodium equivalent to 1000 mg amoxicillin and 238.253 mg potassium clavulanate equivalent to 200 mg clavulanic acid. If reconstituted as recommended, it contains 53.01 mg amoxicillin sodium equivalent to 50 mg amoxicillin and 11.913 mg potassium clavulanate equivalent to 10 mg clavulanic acid per ml.
Excipients: Water for injection in diluent ampoule.

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 medicine when you go to a doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher or lower** dose other than recommended to you.*

In this leaflet:

1. WHAT IS AMOKLAVIN AND WHAT IS IT USED FOR

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

AMOKLAVIN is presented as 1 vial containing almost white to creamy white colored powder for injection and ampoule containing 20 ml of water for injection.

AMOKLAVIN is in the short-term treatment of following infections caused by bacteria susceptible to AMOKLAVIN:

- Upper respiratory tract infections such as recurrent tonsillitis, sinusitis, otitis media
- Lower respiratory tract infections such as acute exacerbations of chronic bronchitis, lung inflammation
- Infections related to reproductive organs and urinary tract such as urinary tract inflammation, urethra (urinary bladder) inflammation, bacterial inflammation of the kidneys
- Skin and soft tissue infections such as boil, abscess (pockets of pus), cellulitis and wound infections

- Dental and gingival infections such as tooth abscess
- Miscarriage due to bacteria or toxins present in blood and tissues, puerperal fever, presence of bacteria and toxins in intra-abdominal blood and tissues.

AMOKLAVIN is also used to prevent infections in major surgical procedures.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE AMOKLAVIN

Do not use AMOKLAVIN

- If you are allergic (hypersensitive) to amoxicillin, clavulanic acid, penicillin or any of the other ingredients of this medicine (see list of excipients).
- 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 an antibiotic.

Take special care with AMOKLAVIN

- If you have glandular fever (a disease caused by viruses, manifesting with high fever, sore throat, extreme weakness and fatigue).
- If you are being treated for liver or kidney problems.
- If you do not urinate regularly.

If these warnings are applicable to you do not use AMOKLAVIN. If you are not sure, talk to your doctor, pharmacist or nurse before taking AMOKLAVIN

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 AMOKLAVIN or a different medicine.

Conditions you need to look out for

AMOKLAVIN can make some existing conditions worse, or cause serious side effects. These include allergic reactions, convulsions (fits that cause unconsciousness and severe contractions in voluntary muscles) and inflammation of the large intestine. You must look out for certain symptoms while you are taking AMOKLAVIN, 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 AMOKLAVIN. This is because AMOKLAVIN can affect the results of these types of tests.

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

Using AMOKLAVIN with food and drink

There is no interaction with food and drinks in terms of administration method.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.
If you are pregnant or think you may be pregnant or are planning to have a baby, ask your

doctor, pharmacist or nurse for advice before taking this medicine.
If you realize that you are pregnant during the treatment, consult your doctor or pharmacist immediately.

Breastfeeding
Consult your doctor or pharmacist before taking this medicine.
If you are breastfeeding ask your doctor, pharmacist or nurse for advice before taking this medicine.

Driving and using machines
AMOKLAVIN may cause undesirable effects and may affect your ability to drive. If you feel unwell, do not drive or use machinery.

Important information about some of the ingredients of AMOKLAVIN
AMOKLAVIN contains 62.9 mg (2.7 mmol) of sodium per vial. To be taken into consideration by patients on a controlled sodium diet.

AMOKLAVIN contains 39.3 mg (1 mmol) of potassium per vial. To be taken into consideration by patients with reduced kidney function or patients on a controlled potassium diet.

Using with other medicines
- If you are taking allopurinol (used to treat gout) with AMOKLAVIN, you may be more likely to develop an allergic skin reaction.
- If you are taking probenecid (used to treat gout), your doctor may decide to adjust your dose of AMOKLAVIN.
- If you are taking medicines to help stop blood clots (such as warfarin) with AMOKLAVIN, you may need to get extra blood tests done.
- AMOKLAVIN may affect the way methotrexate (a medicine used to treat cancer or rheumatic diseases) works.
- AMOKLAVIN may affect the way mycophenolate mofetil (used to prevent the rejection of transplanted organs) works.

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

3. HOW TO USE AMOKLAVIN
Instructions for proper use and dose/frequency of administration
Always use AMOKLAVIN exactly as your doctor has told you to. Consult with your doctor or pharmacist if you are not sure.

Depending on the type of infection you have or need to be protected from, your doctor will determine the dose and frequency of administration of your medicine.

The recommended doses are as follows:

<u>In adults:</u>
1.2 g of AMOKLAVIN is given every 8 hours. If required, your doctor may increase dose of AMOKLAVIN as 1.2 g every 6 hours.

Frequency of administration also depends on the kidney functions.

To prevent surgical infections:
In order to prevent infections in surgeries lasting less than 1 hour, 1.2 g of AMOCLAVIN is given at the beginning of anesthesia. In surgeries lasting longer than 1 hour, this treatment can be continued up to 4 doses in 24 hours.

Route and method of administration:
After preparation, AMOKLAVIN will be administered by the doctor or nurse as an intravenous injection (for 3-4 minutes) or as an intravenous infusion (for 30-40 minutes). Your treatment is not expected to last longer than 14 days until your doctor reassesses your condition.

Different age groups:
Use in children:
The dose depends on the child's weight. Your doctor will determine the AMOKLAVIN dose based on your child's weight and will administer to your child. Adult dose is administered to children weighing more than 40 kg. Recommended doses for children weighing less than 40 kg:
- 30 mg/kg AMOKLAVIN every 8 hours in children aged 3 months and over (may be increased to every 6 hours in very severe infections)
- 30 mg/kg of AMOKLAVIN every 12 hours in children aged less than 3 months or weighing less than 4 kg (may be increased to every 8 hours in more serious infections)

Use in elderly:
No dose adjustment is considered necessary in the elderly.

Use in special conditions
Kidney impairment / Liver impairment
If you have kidney or liver impairment, dose must be adjusted carefully and reduced, if required.

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

If you use more AMOKLAVIN than you should:
As AMOKLAVIN will be administered by a healthcare professional, you are not expected to receive too much. However, if you think you have been administered more AMOKLAVIN than you should, talk to your doctor or nurse. Signs may be an upset stomach (nausea, vomiting or diarrhea) or convulsions (fits that cause unconsciousness and severe contractions in voluntary muscles).

If you have been administered more AMOKLAVIN than you should, talk to your doctor or nurse.

If you forget to use AMOKLAVIN
As AMOKLAVIN will be given by a healthcare professional, you are not expected to forget your dose. However, if you think that your dose has been forgotten, tell your doctor or nurse.

Do not take a double dose to make up for a forgotten dose.

Effects that may occur when treatment with AMOKLAVIN is terminated
The treatment should be continued as long as recommended by your doctor. If the treatment is stopped before its due time, infection may recur or get worse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may be seen in people with sensitivity to ingredients of AMOKLAVIN. The following side effects may be observed with the use of this medicine.

Side effects are classified in the following frequencies:
Very common : may occur in at least 1 in 10 patients
Common : may occur in less than one in 10 patients, but more than one in 100 patients.
Uncommon : may occur in less than one in 100 patients, but more than one in 1,000 patients.
Rare : may occur in less than one in 1,000 patients, but more than one in 10,000 patients.
Very rare : may occur in less than one in 10,000 patients.
Not known : cannot be estimated from the available data.

If any of the following occur, stop using AMOKLAVIN and IMMEDIATELY inform your doctor or go to the nearest hospital emergency department:

- Allergic condition characterized by symptoms such as itchy, red-purple colored spots especially on the soles or palms, urticaria-like swellings on skin, hypersensitivity in mouth, eye and genital area, fever and fatigue (erythema multiforme)
- Swelling and redness along a vein which is extremely tender when touched
- Sudden loss of all strength in the body without fainting (collapse)
- Swelling of the face, lips, mouth, tongue or throat causing difficulty swallowing or breathing (angioneurotic edema)
- Hyperallergic condition characterized by symptoms such as rash, itching or hives on the skin, swelling of face, lips, tongue or other parts of body, shortness of breath, wheezing or difficulty breathing (anaphylaxis)
- Allergic condition characterized by symptoms such as rash, fever, joint pain and especially swelling of glands in armpit 7-12 days after the intake of medicine (serum sickness-like syndrome)
- Inflammation of blood vessels which may be visible as red raised spots on the skin, rash and formation of bruises on skin (hypersensitivity vasculitis)
- A rare skin disease characterized by severe blisters in lips, eyes, mouth, nose and genital area and bleeding (Stevens Johnson Syndrome)
- Severe skin reaction, which starts with painful redness on the skin, then continuing with bigger blisters and ending as peeling of skin in layers. This disease is accompanied by fever, chills, muscle pain and overall feeling unwell (toxic epidermal necrolysis).
- Widespread red skin rash with small pus-containing blisters (bullous exfoliative dermatitis)
- Red, scaly rash with bumps under the skin and blisters (acute generalized exanthemous)
- 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)).

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, and swollen glands in the neck, armpit and groin
- Swelling, sometimes of the face or throat (angioedema), causing difficulty in breathing
- Collapse (a serious breakdown caused by the expansion of the peripheral vessels and the accumulation of blood there, sudden loss of overall body strength)
- Chest pain in the context of allergic reactions, which may be a symptom of allergy triggered cardiac infarction (Kounis syndrome)

Contact a doctor immediately and stop using AMOKLAVIN if you get any of these symptoms.

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

Acute inflammation of the pancreas (acute pancreatitis):
If you have severe and on-going pain in the stomach area this could be a sign of acute pancreatitis.

Drug-induced enterocolitis syndrome (DIES):
DIES has been reported mainly in children receiving amoxicillin/clavulanate. It is a certain kind of allergic reaction with the leading symptom of repetitive vomiting (1-4 hours after drug administration). Further symptoms could comprise abdominal pain, lethargy (constant sleepiness), diarrhea and low blood pressure.

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

These are all very serious side effects.
If you have any of these, it means that you are seriously allergic to AMOKLAVIN. You may need urgent medical attention or hospitalization.

If you notice any of the following, inform your doctor immediately or go to the nearest hospital emergency department:
- Generally bloody, mucous diarrhea due to medicine use.

These are all serious side effects. They may require urgent medical attention.
Serious side effects occur very rarely.

Tell your doctor if you notice any of the following:
Other side effects seen with the use of AMOKLAVIN:

Common:
- Thrush (a yeast infection of the vagina, mouth or skin folds) (mucocutaneous candidiasis)
- Diarrhea

Uncommon:
- Skin rash, itching
- Hives
- Nausea (especially when taking high doses)
- Vomiting
- Indigestion
- Dizziness
- Headache
- Increase in some substances (enzymes) produced by the liver

Rare:
- Swelling and redness along a vein which is extremely tender when touched
- Low number of cells involved in blood clotting
- Low number of white blood cells

Not known:
- Inflammation of the protective membrane surrounding the brain (aseptic meningitis)
- Liver disease characterized by nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of skin and eyes and dark colored urine (hepatitis)
- Yellowing of skin and/or eyes (cholestatic jaundice)
- Inflammation of tubes in the kidneys
- Prolongation of blood clotting time
- Convulsions (in people taking high doses of AMOKLAVIN or who have kidney problems).
- Severe reduction in the number of white blood cells
- Low number of red blood cells (hemolytic anemia)
- Crystals in urine (leading to acute kidney injury)
- Rash with blisters arranged in a circle with central crusting or like a string of pearls (linear IgA disease)
- Inflammation of the protective membranes surrounding the brain and spinal cord (aseptic meningitis)
- 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)).

These are mild side effects of AMOKLAVIN.

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.

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

5. HOW TO STORE AMOKLAVIN

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

Dry powder should be stored at room temperature below 25°C.

After reconstitution, the product should be used immediately.

Use it in line with the expiry date.

Do not use AMOKLAVIN 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

Diluent Manufacturing Site:
DEVA Holding A.Ş.
Kartepe – KOCAELİ / TÜRKİYE

This package leaflet was last approved on 15/01/2024.

FOLLOWING INFORMATION IS FOR HEALTHCARE PROFESSIONALS ONLY

Please refer to the Summary of Product Characteristics for further information.

AMOKLAVIN is for intravenous use. AMOKLAVIN is not suitable for intramuscular administration.

Administration
AMOKLAVIN is dissolved in diluent (20 ml water for injection) accompanying the product. It should be administered either by injection directly into a vein over a period of 3 to 4 min or via a drip tube or by infusion over 30 to 40 minutes.

Reconstitution
For single use only. Discard any unused solution.
The reconstitution/dilution is to be made under aseptic conditions. The solution is to be inspected visually for particulate matter and discoloration prior to administration. The solution should only be used if the solution is clear and free from particles. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Preparation of solutions for intravenous injection
AMOKLAVIN is dissolved in diluent (20 ml water for injection) accompanying the product. The intravenous injection should be administered within 20 minutes of reconstitution.

Preparation of solutions for intravenous infusion
AMOKLAVIN is not suitable for multi-dose use.
AMOKLAVIN is dissolved in diluent (20 ml water for injection) accompanying the product and should be added to 100 ml of infusion solution without delay.

Stability of prepared solutions
Reconstituted vials (for intravenous injection or before dilution for infusion)
AMOKLAVIN should be administered within 20 min of reconstitution.

Time periods for intravenous infusion with different diluents are given below:

Compatible infusion solutions with AMOKLAVIN	**Stability period**
Water for injection	2 hours
Sodium chloride 0.9%	2 hours
Sodium lactate (M/6)	1 hour
Ringer's solution	1 hour
Lactated Ringer's Solution	1 hour
Potassium chloride and sodium chloride intravenous infusion	1 hour

AMOKLAVIN is less stable in infusions containing glucose, dextran or bicarbonate. Therefore, AMOKLAVIN should not be added to such infusions but should be injected into the drip tubing over a period of 3-4 minutes.

Any remaining antibiotic solution should be discarded.