PATIENT INFORMATION LEAFLET

AMIKAVER 100 mg/2 mL I.M./I.V. Solution for Injection

Sterile

It is administered by intramuscular or intravenous.

Active ingredients: Each 2 mL ampoule contains amikacin sulfate equivalent to 100 mg amikacin.

Excipients: Sodium metabisulfite, sodium citrate, water for injection and sulphuric acid (pH adjustment).

Read all of this PATIENT INFORMATION 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 medication is prescribed solely for you, do not offer it to others.*
- *If you go to doctor or hospital while using this medicine, tell your doctor that you are using this medicine.*
- *Follow the recommendations on this leaflet exactly as described. Do not use **higher or lower dose** except the dose you have been recommended for the medicine.*

In this Information Leaflet:

headings are included.

1. What AMIKAVER is and what it is used for?

This medicine is called AMIKAVER. Each 2 mL ampoule contains 100 mg amikacin sulphate as drug substance.

Amikacin is an antibiotic and belongs to a medicine group called aminoglycosides. AMIKAVER is used for treating severe infections caused by bacteria.

2. Before taking AMIKAVER

DO NOT USE AMIKAVER if:

- You are allergic to the substances in AMIKAVER or allergic to (hypersensitive) antibiotics
- You have Myasthenia gravis (a disease causing muscle weakness)

If above stated conditions apply to you or if you are unsure whether they apply to you or not, please consult to your doctor for advice.

USE AMIKAVER CAUTIOUSLY in the following conditions:

- If you have a problem with your kidneys
- If you had experienced kidney or hearing problems after using other antibiotics
- If you have a muscle disease such as Parkinson's Disease

AMIKAVER will not be administered to your stomach by injection until the effects of anaesthetic or myorelaxant medicines' wear off. Because this administration might cause breathing problems.

It is not advised to administer AMIKAVER to small children via injection to stomach.

Even if such warnings were present for any period in the past, please consult your doctor.

Using AMIKAVER with food or beverage

No interaction with food or drink is expected due to administration method.

Pregnancy

Consult your doctor or pharmacist before taking this medicine.

If you are pregnant or think that you might be pregnant,consult to your doctor before taking AMIKAVER.

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

Breast-feeding

Consult your doctor or pharmacist before taking this medicine.

It is not known whether amikacin is excreted in human milk. A decision should be made on whether breastfeeding or treatment should be discontinued.

Driving and using machines

AMIKAVER injection does not affect your ability to use vehicles or machines.

Important information about some of the ingredients of AMIKAVER

This product contains 2.6 mg sodium metabisulphite. Rarely, might cause hypersensitivity reactions (probably delayed) and bronchospasm (narrowing of bronchi). This medicinal product contains less than 1 mmol sodium (23 mg) per mL, i.e. can be considered as 'sodium-free'.

Using with other medicines

Please tell your doctor or pharmacist any other medicine that you are currently using or have used recently, including over-the-counter medicines. Some medicines might have effect on other medicines. If you are using the medicines listed below, it is especially important that your notify these to your doctor:

• Diuretics; for example furosemide (tablets or injection)
• Penicillin type antibiotics
• Myorelaxant

Indomethacin (an anti-inflammatory medicine) might increase the amount of absorbed AMIKAVER in newborn babies.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or non-prescription medicines.

3. How to use AMIKAVER

- **Instructions for proper use and dose/frequency of administration:**

Adults: Normal dose is 250 – 500 mg twice a day.
Doses might be increased in some infections.

- **Route and method of administration:**

AMIKAVER is administered intramuscular or intravenously, or sometimes by injection to abdomen.

- **Different age groups:**

Use in children:

Children: Normal dose is 15 mg/day per each 1 kilogram of body weight.
It is administered as a single dose or as two doses of 7.5 mg, one per 12 hours. The total daily dose should not exceed 1.5 g.

Use in elderly:

Amikacin is excreted via kidneys. Kidney function should be assessed whenever possible and the dosage should be adjusted as described in elderly patients with impaired renal function.

- **Special conditions for use:**

Renal or hepatic impairment

While taking AMIKAVER, you might need hearing and kidney tests along with blood tests to control the amount of taken amikacin.

If you notice that the effect of AMIKAVER is too strong or weak, consult your doctor or pharmacist.

If you use more AMIKAVER than you should:

AMIKAVER injection will be made by a qualified healthcare professional (doctor or nurse) who will make the right dose adjustment. In rare cases, more AMIKAVER than necessary might be administered to you. In such a case, your doctor will make sure that the excess dose is eliminated from your blood so that you do not experience many side effects.

If you have taken AMIKAVER more than you should, consult a doctor or pharmacist.

If you forget to use AMIKAVER

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

If you stop taking AMIKAVER

Do not discontinue your treatment without consulting your doctor.

4. What are the possible side effects?

Like all other dugs, side effects can be seen in people that are sensitive to the ingredients of AMIKAVER.

Side effects are usually classified as follows:

Very common : may affect more than 1 in 10 people.
Common : may affect fewer than 1 in 10, but more than 1 in 100 patients. Uncommon : may affect fewer than 1 in 100, but more than 1 in 1,000 people.
Rare : may affect fewer than 1 in 1,000, but more than 1 in 10,000 people.
Very rare : may affect up to 1 in 10,000 people
Not known : Cannot be estimated from available data.

Nervous system disorders:

Unknown: Sudden muscle paralysis

Eye disorders:

Unknown: Direct injection to eye ball might be required and this might cause eye disorders.

Ear and labyrinth disorders:

Unknown: Tinnitus, dizziness, partial reversible or irreversible deafness,

Respiratory and pulmonary disorders

Unknown: Short cessation of breathing (apnoea), bronchospasm (narrowing of bronchi)

Gastrointestinal disorders:

Unknown: Nausea and vomiting

Skin and subcutaneous tissue disorders:

Unknown: Severe hypersensitivity reactions

Renal and urinary disorders:

Unknown: Kidney problems such as decrease in amount of urine, presence of nitrogen in blood (azotemia), presence of albumin in urine (albuminuria), presence of white and red blood cells, increased levels of serum keratin levels.

General disorders and administration site conditions:

Unknown: Skin rash, medicine fever, tingling, increase number of eosinophile (white blood cell: a type that takes part in immune system responses), pain in joints (arthralgia), anemia and decreased blood pressure (hypotension)

It may rarely cause severe hypersensitivity reactions and bronchospasm. If one of the side effects become severe or if you notice any side effect not mentioned in this product information leaflet, please immediately talk to your doctor or pharmacist. Taking note of what you have experienced, when symptoms started and how long they lasted for will help.

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

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly to Turkish Pharmacovigilance Centre (TUFAM) by clicking on the icon "İlaç Yan Etki Bildirimi" (Reporting of Drug Side Effects) on the website www.titck.gov.tr or by calling the side effect reporting line on 0 500 314 00 08. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store AMIKAVER

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

Store between 15°C and 30°C.

Do not use after expiry date indicated on the package.

Please use this medicine accordingly with its expiry date.

Do not use AMIKAVER after expiration date indicated on the package.

Registration Holder and Manufacturing site: OSEL Ilac San. ve Tic. A.S.
Akbaba Mah. Maras Cad. No.:52
Beykoz/Istanbul
Tel: +9 (0216) 320 45 50
Faks: +9 (0216) 320 45 56

This patient information leaflet was approved on 03/12/2014.

FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS WHO WILL ADMINISTER THIS DRUG.

A summary of dosage and administration of AMIKAVER is provided below:

DOSAGE AND ADMINISTRATION

At the recommended dose level, uncomplicated infections due to susceptible organisms should respond to treatment within 24 to 48 hours.

If no clinical response is achieved within 3 to 5 days, alternative treatment should be considered.

Intramuscular or intravenous administration:

Although intramuscular route is preferred for most infections, intravenous administration may be performed as slow bolus (2 to 3 minutes) or infusion (0.25% in 30 minutes) in patients with life-threatening infections or to whom intramuscular injection could not be administered.

Adults and children:

15 mg/kg/day divided into two equal doses (equivalent to 500 mg twice daily in adults). Use of 100 mg/2 mL dosage power is recommended in children for the measurement of the correct dose.

Newborn and premature babies:

Following the 10 mg/kg initial loading dose, 15/mg/kg/day divided into two equal doses.

Elderly:

Since amikacin is eliminated via kidneys, Kidney function should be whenever possible and the dosage should be adjusted as described in impaired renal function.

Life-threatening infections and/or infections of Pseudomonas origin:

Adult dose can be increased to 500 mg in every 8 hours, but not more than 1.5 g per day or more than 10 days. In total, a maximum adult dose of 15 g should not be exceeded.

Urinary tract infections (except pseudomonas infections)

7.5 mg/kg/day divided into two equal doses (equivalent to 250 mg twice daily in adults). As the activity of amikacin is increased by increasing the pH, a urinary alkalizing agent may be administered simultaneously.

Impaired renal function:

In patients with impaired renal function, the daily dose should be reduced and/or the intervals between doses should be increased to prevent accumulation of the drug. Critical serum keratin concentration is 1.5 mg/100 mL. A recommended method for calculating the dose in patients with a known or suspected reduction in kidney function is to multiply the serum creatinine concentration (in mg/100 mL) by 9 and use the obtained number as the interval between the doses in hours.

As kidney function can be visibly changed during treatment, the serum creatinine value should be measured frequently and the dosage regimen should be adjusted as required.

Other routes of administration

AMIKAVER can be used effectively at a concentration of 0.25% (2.5 mg/mL) as irrigation solution in the abscess cavities, pleural space, peritoneum and cerebral ventricles.