PATIENT INFORMATION LEAFLET

AMIKAVER 500 mg/2 mL I.M./I.V. Solution for Injection

It is administered by intramuscular or intravenous.

Active ingredients: Each 2 ml ampoule contains amikacin sulfate equivalent to 500 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 is it used for?

The name of this medicine is AMIKAVER. Each box content one ampule of 2 mL contains 500 mg amikacin sulfate as the drug substance.

Amikacin is an antibiotic and belongs to a group of medicines called aminoglycoside.

AMIKAVER is used to treat serious infections caused by certain bacteria.

2. What you need to know before you use AMIKAVER?

DO NOT USE AMIKAVER in the following situations:

• If you are allergic (hypersensitive) to the substances in AMIKAVER or other antibiotics,

• If you have myasthenia gravis (a disease that causes muscle weakness).

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

Use AMIKAVER CAREFULLY in the following situations:

• If you have any kidney problems

• If you have had kidney or hearing problems after using other antibiotics

• If you have a muscle disorder such as Parkinson's disease

AMIKAVER will not be injected to your stomach until the effects of anesthetic or muscle relaxant drugs (eg. Following surgery) are eliminated, as this administration may lead to breathing problems.

It is not recommended to administer AMIKAVER by injection into the stomach in young children.

Please consult to your doctor if these warnings are applicable for you, even at any time in the past.

Use of AMIKAVER with food and drinks

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

Pregnancy

Talk to your doctor or your pharmacist before using this medicine.

You should talk to your doctor before using AMIKAVER, if you are pregnant or think you may be pregnant.

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

Breast-feeding

Talk to your doctor or your pharmacist before using this medicine.

It is not known whether amikacin is excreted in breast milk. A decision must be made on whether to discontinue the breast-feeding or treatment.

Driving and using machines

AMIKAVER injection will not affect your ability to drive or use machines.

Important information about some excipients present in AMIKAVER

This product contains 13.2 mg of sodium metabisulphite. In rare cases it may cause severe hypersensitivity reactions and bronchospasm.

This medicinal product contains sodium of less than 1 mmol (23 mg) in each dose, i.e. it is essentially sodium-free.

Use with other medicines

Always inform your doctor or pharmacist of any other medications that you are using or have recently used, including non-prescription drugs. Some drugs may have an impact on the effect of other drugs. It is especially important that you tell your doctor if you are taking any of the following drugs:

• Diuretics; eg, furosemide (tablet or injection)
• Penicillin antibiotics
• Muscle relaxants

Indomethacin (an anti-inflammatory drug) may increase the amount of AMIKAVER absorbed in newborn infants.

If you are using or have recently used any medicine with or without a prescription, please inform your doctor or pharmacist about these medicines.

3. How to use AMIKAVER?

- **Instructions for appropriate use and dose/administration frequency:**

Adults: The usual dose is 250 to 500 mg twice daily. Doses may be increased for some infections.

- **Route and method of administration:**

AMIKAVER is administered by injection into a muscle or vein or sometimes to the abdomen.

- **Various age groups:**

Use in children:

Children: The usual dose is 15 mg/day per 1 kg body weight daily and administered as a single dose or divided into two equal doses of 7.5 mg every 12 hours. The total daily dose should not exceed 1.5 gr.

Use in elderly:

Amikacin is excreted by the renal route. Renal function should be assessed whenever possible and dosage in elderly patients should be adjusted as described under impaired renal function.

- **Special conditions of use:**

Renal and hepatic insufficiency:

When using AMIKAVER, you may need to undergo blood tests as well as hearing and kidney tests to check the amount of amikacin received.

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

If you have used more AMIKAVER than you should:

AMIKAVER injection will be performed by a qualified healthcare professional (doctor or nurse) who will ensure the correct dose is administered. In rare cases, you might have redundant AMIKAVER injections. In such a case, your doctor will ensure that this excess dose is removed from your blood to prevent too many side effects.

If you take more AMIKAVER than you should, talk to a doctor or pharmacist.

If you forgot to use AMIKAVER

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

Possible effects that may occur when treatment with AMIKAVER is discontinued

Do not terminate your treatment without consulting your doctor.

4. Possible side effects

As with all medicines, there may be side effects in people who are sensitive to the ingredients of AMIKAVER.

Side effect frequencies are classified as follows:

Very common : may effect more than 1 in 10 patients.
Common : may effect less than one in 10 patients, but more than one in 100 patients.
Uncommon : may effect less than one in 100 patients, but more than one in 1,000 patients.
Rare : may affect less than one in 1,000 patients, but more than one in 10,000 patients.
Very rare : may effect less than one in 10,000 patients.
Unknown : frequency cannot be estimated from the available data.

Nervous system disorders:

Unknown: Sudden muscle paralysis

Eye disorders:

Unknown: It may need to be injected directly into the eyeball and may cause visual impairment.

Ear and labyrinth disorders:

Unknown: Tinnitus, dizziness, partial reversible or irreversible deafness

Respiratory, chest disorders:

Unknown: Short duration of respiratory arrest (apnea), bronchospasm (narrowing of the bronchi)

Gastrointestinal disorders:

Unknown: Nausea and vomiting

Skin and subcutaneous tissue disorders:

Unknown: Severe hypersensitivity reactions

Renal and urinary disorders:

Unknown: Renal problems such as reduced urine volume, presence of nitrogen in the blood (azotemia), presence of albumin in the urine (albuminuria), presence of red and white blood cells in the urine, increase in serum creatinine levels

General disorders and administration site conditions:

Unknown: Skin rash, drug-related fever, headache, tingling, increase in eosinophil count (white blood cell: a type of blood cell involved in immune system responses), joint pain (arthralgia), anemia and decreased blood pressure (hypotension)

Also, severe hypersensitivity reactions and bronchospasm may occur in rare cases. If any of the side effects become serious or if you notice any side effects not listed in this patient information leaflet, please talk to your doctor or pharmacist. It will be helpful for you to note down what you have experienced, when it started and how long it lasted.

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

5. How to store AMIKAVER

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

Store at between 15 ºC - 30ºC.

Do not use the drug after the expiration date indicated on the packaging.
Use in accordance with expiration dates.

Do not use AMIKAVER after the expiration date stated on the packaging.

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INFORMATION BELOW IS FOR THE HEALTHCARE PROFESSIONAL WHO WILL ADMINISTER THIS MEDICINAL PRODUCT

The summary of the dosage and administration of AMIKAVER is given below.

DOSAGE AND ADMINISTRATION:

At the recommended dosage level, uncomplicated infections due to sensitive organisms should respond to therapy 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:

For most infections the intramuscular route is preferred, but in life-threatening infections, or in patients in whom intramuscular injection is not feasible the intravenous route, either slow bolus (2 to 3 minutes) or infusion (0.25% over 30 minutes) may be used.

Adults and children:

15 mg/kg/day divided into two equal doses (equivalent to 500 mg twice daily in adults): It is recommended to use dose strength of 100 mg/2 mL in children for accurate measurement of the appropriate dose.

Neonates and premature infants:

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

Elderly:

As amikacin is excreted through kidneys, renal function should be assessed whenever possible and dosage should be adjusted as described under impaired renal function.

Life-threatening infections and/or those caused by Pseudomonas:

The adult dose may be increased to 500 mg every 8 hours but should neither exceed 1.5 gr/day nor be administered for a period longer than 10 days. A maximum total adult dose of 15 gr should not be exceeded.

Urinary tract infections (other than pseudomonal 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 enhanced by increasing the pH, a urinary alkalizing agent may be

administered concurrently.

Impaired renal function:

In order to prevent the accumulation of the drug, daily doses should be reduced and/or intervals between the doses should be prolonged in patients with impaired renal function. Critical serum creatinine concentration is 1.5 mg/100 mL. A recommended method for calculating the dose in patients with a known or suspected reduction in renal function is multiplying the patient's serum creatinine concentration (in mg/100 ml) by 9 and using the obtained number as a dosage interval in hours.

As renal function may alter appreciably during therapy, the serum creatinine value should be checked frequently and the dosage regimen modified as necessary.

Other routes of administration

AMİKAVER in a concentration of 0.25% (2.5 mg/ml) can be effectively used as an irrigating solution in abscess cavities, the pleural space, the peritoneum and the cerebral ventricles.