When amikacin is indicated in uncomplicated urinary tract infections, a dose of 250 mg twice daily may be used.

Recommended dosage level, uncomplicated infections due to amikacin-sensitive organisms should respond in 24 to 48 hours. If definite clinical response is not indicated within these time limits, a reevaluation of therapy is recommended.

When amikacin is indicated in newborns (see Precautions), the following guidelines are suggested. 

- For infants up to 3 months of age: 7.5 to 10 mg/kg per 12-hour interval. 
- For infants over 3 months of age: 5 to 7.5 mg/kg per 12-hour interval.

To report SUSPECTED ADVERSE REACTIONS, contact Sagent Pharmaceuticals, Inc. at 1-866-625-1618 or FDA at 1-800-FDA-1088.

Cross-allergenicity among aminoglycosides has been demonstrated.

The importance of the drug to the mother.

Other antibacterial drugs in the future.

Clearance determination may be more useful. Monitoring of renal function during treatment with aminoglycosides is particularly important.

Since amikacin is present in high concentrations in the renal excretory system, patients should be well hydrated to minimize chemical irritation of the renal surgical field with an aminoglycoside preparation.

General

Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; CLSI document M02-A12, Clinical and Laboratory Standards Institute, 950 West Valley Road, Suite 2500, Wayne, PA 19087-1517, 2016.

Susceptibility testing should be performed by standardized methods. The National Committee for Clinical Laboratory Standards provides standards for performance of the disk diffusion assay and the broth dilution assay (NCCLS document M7-A7 and M100-S16, 2016). These standards detail how to perform dilution and disk diffusion susceptibility tests and how to interpret the results.

An alternate rough guide for determining reduced dosage at 12-hour intervals (for patients whose steady state serum creatinine values are known) is to take 1/2 of the usual dose or to reduce the interval at which the drug is given. Whenever possible, serum amikacin concentrations should be monitored by appropriate assay procedures. Doses may be adjusted in patients with renal insufficiency and whenever there is doubt about the adequacy of the dosage. The dosage requirement in patients with renal insufficiency may be determined by measuring serum amikacin concentrations. These concentrations should be determined at least 30 minutes after completion of an infusion and 12 hours after the equivalent of a single dose. Amikacin accumulates in patients with impaired renal function and the dosage should be reduced accordingly.

Whenever possible, serum amikacin concentrations should be monitored by appropriate assay procedures. Doses may be adjusted in patients with renal insufficiency and whenever there is doubt about the adequacy of the dosage.

The above dosage schedules are not intended to be rigid recommendations but are provided as guides to dosage when the measurement of amikacin serum levels is not feasible.

Mechanism of Resistance

The majority of amikacin-resistant strains are produced by acquisition of plasmid encoding the aminoglycoside modifying enzymes, which alter the drug at the site of action, and render it biologically ineffective. Cross-resistance usually occurs between aminoglycosides and other antibiotics that share the same mode of action. It is important to choose an appropriate antibiotic based on the susceptibility tests.

Table 2: Acceptable Quality Control Ranges for Amikacin

<table>
<thead>
<tr>
<th>Concentration (mcg/mL)</th>
<th>SIR</th>
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<th>SIR</th>
<th>SIR</th>
<th>SIR</th>
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</thead>
<tbody>
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<td>32</td>
<td>64</td>
<td>128</td>
<td>256</td>
<td>512</td>
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<tr>
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<td>128</td>
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<tr>
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<td>64</td>
<td>128</td>
<td>256</td>
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</tbody>
</table>

In vitro susceptibility test results should be interpreted according to the criteria provided in Table 2. The Clinical Laboratory Standards Institute has defined a resistant breakpoint of 4 mcg/mL for amikacin.

In vitro susceptibility test results should be interpreted according to the criteria provided in Table 2. The Clinical Laboratory Standards Institute has defined a resistant breakpoint of 4 mcg/mL for amikacin.
Aminoglycosides should be used with caution in premature and neonatal infants because of the renal immaturity of these patients and the resulting account the importance of the drug to the mother. Long term studies in animals to evaluate carcinogenic potential have not been performed, and mutagenicity has not been studied. Amikacin administered Information for Patients dosage recommendations (see DOSAGE AND ADMINISTRATION) are not exceeded.

Prescribing amikacin in the absence of a proven or strongly suspected bacterial infection or a prophylactic indication is unlikely to provide benefit to the patient. A history of hypersensitivity to amikacin is a contraindication for its use. A history of hypersensitivity or serious toxic reactions to aminoglycosides may indicate that amikacin should be avoided.

CONTRAINDICATIONS

The container closure is not made with natural rubber latex.

Aminoglycosides and related aminoglycosides are contraindicated in patients with a history of hypersensitivity to any of these agents or to other related aminoglycosides. A history of hypersensitivity or serious toxic reactions to aminoglycosides may indicate that amikacin should be avoided.

Because amikacin is eliminated primarily by the kidneys, care should be exercised in using amikacin in patients with impaired renal function. In such patients, dosage adjustments are necessary. The possibility of these phenomena should be considered if aminoglycosides are administered by any route, especially in the presence of renal impairment. Amikacin is contraindicated in patients with diminished renal function who are also receiving aminoglycosides or other drugs, such as those that may be tubular toxic (e.g., cisplatin). Amikacin is contraindicated in patients with renal failure (creatinine clearance rate <30 ml/min) who are also receiving aminoglycosides or other nephrotoxic drugs. Amikacin is contraindicated in patients with severe renal disease who are also receiving aminoglycosides or other drugs, such as those that may be tubular toxic (e.g., cisplatin). Amikacin is contraindicated in patients who are also receiving drugs, such as those that may be tubular toxic (e.g., cisplatin).

Amikacin is not indicated in uncomplicated initial episodes of urinary tract infections unless the causative organisms are not susceptible to antibiotics having documented activity against the organisms causing the infection.

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