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PHARMACOLOGY

Intravenous Administration

- Amikacin is rapidly absorbed after intravenous administration, with peak concentrations occurring within 30 minutes. The mean peak serum concentration (Cmax) was 28 mcg/mL at an intravenous dose of 7.5 mg/kg for a drug concentration of 15 mg/mL. Renal and eighth-nerve function should be closely monitored especially in patients with anuria, oliguria, or those requiring renal dialysis.

- Intramuscular administration of amikacin sulfate is not recommended due to erratic absorption and variable peak serum levels.

Dosage and Administration

- Intravenous administration:
  - Adults: The usual initial dose is 15 mg/kg administered as a single dose for serious infections. For less serious infections, 7.5 mg/kg may be used. The dose can be repeated every 8 to 12 hours, depending on the severity of the infection.
  - Children: The usual initial dose for children is 15 mg/kg administered as a single dose for serious infections. For less serious infections, 7.5 mg/kg may be used. The dose can be repeated every 8 to 12 hours, depending on the severity of the infection.

- Intramuscular administration:
  - Adults: The usual initial dose is 15 mg/kg administered as a single dose for serious infections. For less serious infections, 7.5 mg/kg may be used. The dose can be repeated every 8 to 12 hours, depending on the severity of the infection.
  - Children: The usual initial dose for children is 15 mg/kg administered as a single dose for serious infections. For less serious infections, 7.5 mg/kg may be used. The dose can be repeated every 8 to 12 hours, depending on the severity of the infection.

- The use of an aminoglycoside preparation as an adjuvant to other antipseudomonal drugs, including cephalosporins and carbapenem antibiotics, is recommended for patients with infection due to Pseudomonas aeruginosa when used in combination with an antipseudomonal beta-lactam antibiotic and is likely to be more effective than aminoglycoside monotherapy.

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Information for Patients

WARNINGS

Neurotoxicity - Neuromuscular Blockade

All aminoglycosides have the potential to induce auditory, vestibular, and renal toxicity. This is dose-related and occurs in patients with normal renal function up to several times the usual dosage. Patients with impaired renal function or especially those with severe impairment may be at greater risk of toxicity. The potential for auditory toxicity is greatest in patients on long-term therapy, especially those with ototoxic drugs in the future.

Aminoglycosides should be used with caution in patients with muscular disorders, including critical illness polyneuropathy or myopathy. Drugs that block the neuronal sodium channel may mask signs of myopathy (e.g., weakness or muscle stiffness). If myopathy occurs, aminoglycosides should be discontinued. The possibility of toxicity should be considered if hearing loss, loss of balance, or both are noted in patients on long-term therapy.

Allergic reactions may be manifested by skin rashes, fever, chills, hypotension, or shock. Reactions may range from mild to life-threatening. With aminoglycosides, anaphylactoid reactions are more common than those produced by penicillin. The usual consequences of anaphylactic reactions to aminoglycosides are bronchospasm, hypotension, laryngeal edema, and anuria. In very rare instances, fatal anaphylactoid reactions have been reported. Cross-sensitivity among aminoglycosides may be demonstrated.

Aminoglycosides are contraindicated in patients with a history of idiosyncrasy to any aminoglycoside. Patients with a history of renal impairment or hearing loss should not receive an aminoglycoside. Severe and frequently fatal hearing loss has occurred in patients with pre-existing hearing loss or in those with normal hearing who have been exposed to aminoglycosides at high dosage levels.

Patients with normal renal function should be observed for evidence of auditory and vestibular toxicity. Evidence of toxicity includes hearing loss, loss of balance, or both. If such toxicity occurs, treatment should be stopped.

Monitoring of renal function during treatment with amikacin is desirable. Since amikacin is present in high concentrations in the renal excretory system, patients with renal impairment are at increased risk of developing nephrotoxicity.

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