

Only for the use of Medical Professionals

Kacin[®]

Amikacin

Presentation

Kacin[®] 100 mg Injection: Each 2ml ampoule contains Amikacin 100 mg as Sulfate USP.

Kacin[®] 500 mg Injection: Each 2 ml ampoule contains Amikacin 500 mg as Sulfate USP.

"At times the solution may become a very pale yellow; this does not indicate a decrease in potency".

Uses

Kacin[®] is a semi-synthetic aminoglycosidic antibiotic, indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria. Kacin[®] is effective in bacterial septicemia (including neonatal sepsis); in serious infections of the respiratory tract, bones and joints, central nervous system (including meningitis) and skin and soft tissue; intra abdominal infections (including peritonitis); and in burns and post operative infections (including postvascular surgery). Kacin[®] is also effective in serious complicated and recurrent urinary tract infections due to susceptible Gram-negative organisms. Kacin[®] may be considered as initial therapy in suspected Gram-negative infections and therapy may be instituted before obtaining the results of susceptibility. **Kacin[®] is also effective in infections caused by Gentamycin and/or Tobramycin resistant strains of Gram-negative organisms.** Kacin[®] has also been shown to be effective in Staphylococcal infection and may be considered as initial therapy under certain condition in the treatment of known suspected Staphylococcal disease such as, severe infections where the causative organism may either a Gram-negative bacterium or Staphylococcus infection due to susceptible strains of Staphylococcal / Gram-negative infections. In certain severe infections such as neonatal sepsis, concomitant therapy with a penicillin type drug may be indicated because of the possibility of infections due to Gram positive organism such as streptococci or pneumococci.

Dosage and Administration

Adults and children: 15 mg/ kg/ day in two equally divided doses (equivalent to 500 mg bid in adults). Use of the 100 mg/ 2 ml strength is recommended for children for the accurate measurement of the appropriate dose.

Neonates and premature children: An initial loading dose of 10 mg/kg followed by 15 mg/ kg/ day in two equally divided doses.

Elderly: Doses should be adjusted under impaired renal function in elderly:

Life-threatening infections and/ or those caused by pseudomonas: The adult dose may be increased to 500 mg every eight hours but should neither exceed 1.5 gm/ day nor be administered for a period longer than 10 days. A maximum total adult dose of 15 gm should not be exceeded.

Urinary tract infections: (Other than pseudomonal infections): 7.5 mg/kg/ day in two equally divided doses (equivalent to 250 mg bid in adults).

Impaired renal function: In patient with impaired renal function the daily dose should be reduced and / or the intervals between doses increased to avoid accumulation of the drug. Simple doses schedule for renal impairment is given below:

Renal function	Dose schedule
Mild impairment	500 mg every 18 hours
Moderate impairment	500 mg every 24 hours
Severe impairment	250 mg every 24 hours

Administration:

Intramuscular or intravenous administration: For most infections the intramuscular route is preferred, but in life threatening infections, or in patients in whom intramuscular injection route is not feasible the intravenous route may be used.

Intraperitoneal use: Kacin® may be used as an irrigant after recovery from anaesthesia in concentration of 0.25%.

Other route of administration: Kacin® in concentration of 0.25% may be used satisfactorily as an irrigating solution in abscess cavities, the pleural space, the peritoneum and the cerebral ventricles.

Contra-indications, warnings, etc.

Contra-indications: A history of hypersensitivity or serious toxic reaction to aminoglycosides may contraindicate the use of Kacin®.

Use in pregnancy and lactation: The safety of Kacin® in pregnancy has not yet been established.

Side-effects: When the recommended precautions and dosages are followed the incidence of toxic reactions, such as tinnitus vertigo, and partial reversible or irreversible deafness, skin rash, drug fever, headache, paraesthesia, nausea and vomiting is low. Urinary signs of renal irritation, azotaemia and oliguria have been reported.

Overdose: In the event of overdose or toxic reaction, peritoneal dialysis or haemodialysis will aid in the removal of Kacin® from the blood.

Pharmaceutical precautions

Store in a cool and dry place. Protect from light.

Package quantities

Kacin® 100 mg Injection: Carton of 20 ampoules in plastic trays.

Kacin® 500 mg Injection: Carton of 10 ampoules in plastic trays.

® Registered Trade Mark



ACI Limited