Amibac™

Amikacin 100 mg & 500 mg Injection

Presentation
Amibac™ 100 IM/IV injection: Each 2 ml injection contains Amikacin Sulfate USP equivalent to 100 mg Amikacin.
Amibac™ IM/IV injection: Each 2 ml injection contains Amikacin Sulfate USP equivalent to 500 mg Amikacin.

Description
Amikacin is a semi-synthetic Aminoglycoside with a broad antimicrobial activity and exhibits resistance to Aminoglycoside-inactivating enzymes. It is bactericidal and is minimally protein bound.

Indications
Amikacin is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria. Amikacin injection 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 post vascular surgery). Amikacin is also effective in serious complicated and recurrent urinary tract infections due to susceptible strains of Gram-negative organisms. Amikacin may be considered as initial therapy in suspected Gram-negative infections and therapy may be instituted before obtaining the results of susceptibility. Amikacin is also effective in infections caused by Gentamicin and/or Tobramycin-resistant strains of Gram-negative organisms. Amikacin has also been shown to be effective in Staphylococcal infections and may be considered as initial therapy under certain conditions in the treatment of known or suspected Staphylococcal diseases such as, severe infections where the causative organism may be either a Gram-negative bacterium or a *Staphylococcus*, infections due to susceptible strains of *Staphylococci* in patients allergic to other antibiotics, and in mixed 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 organisms, 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 functions:* In patient with impaired renal function the daily dose should be reduced and/or the intervals between doses be increased to avoid accumulation of the drug. Simple doses schedule for renal impairment is given below: *Mild impairment:* 500 mg every 18 hours; *Moderate impairment:* 500 mg every 24 hours; *Severe impairment:* 250 mg every 24 hours. *Intramuscular or intravenous administration:* For most infections the intramuscular route is preferred, but in the life threatening infections or in patients in whom intramuscular injection route is not feasible, the intravenous route may be used.

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

Contraindications
Amikacin injection is contraindicated in patients with a known history of hypersensitivity to Amikacin.

Drug Interactions
Concurrent administration of Amikacin with myorelaxants leads to potentiation of their effects and there is a possibility of cessation of the breathing. The combination with other Aminoglycoside antibiotics should be avoided because of the augmentation of their ototoxic and nephrotoxic effects. Concurrent administration of Amikacin with fast acting diuretics increases the risk of ototoxicity in patients with renal failure. Combination with Cephalosporins or Polymixins increases the risk of nephrotoxicity.

Precautions
In high plasma concentrations of the drug, there is an increased risk of ototoxicity and kidney toxicity, because of which a monitoring of the peak plasma concentration is advised. Amikacin should be prescribed with increased caution in patients suffering from parkinsonism, diseases of the auditory nerve, myasthenia gravis, severe renal and hepatic insufficiency. In cases of prolonged treatment, regular checks of the state of hearing and creatinine clearance are advised. The treatment should be discontinued in cases of loss of hearing of high frequency sounds. *Use in Pregnancy:* Pregnancy category D. The safety of Amikacin in pregnancy has not yet been established. *Use in Lactation:* It is not known whether Amikacin is excreted in breast milk. Since the possible harmful effect on the infant is not known, it is recommended that if nursing mothers must be given Amikacin, the infants should not be breast fed during therapy.

Overdosage
In the event of overdose or toxic reaction, peritoneal dialysis or haemodialysis will aid in the removal of Amikacin from the blood.

Pharmaceutical Precautions
Store in a cool dry place protected from light. Keep out of reach of children.

Commercial Packs
Amibac™ 100 IM/IV injection: Each box contains 2X5 ampoules in blister pack.
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Manufactured by :

POPULAR

POPULAR PHARMACEUTICALS LTD.
TONGI, GAZIPUR, BANGLADESH