Amikacin is a semi-synthetic antibiotic belonging to the aminoglycosides group.

INDICATIONS

PIERAMI is active against a broad spectrum of Gram-negative (Pseudomonas, Escherichia coli, indole-positive and indole-negative Proteus, Salmonella and Shigella, Klebsiella, Enterobacter, Serratia, Providencia, Citrobacter) and against several Gram-positive germs (Staphylococcus aureus producing and not producing penicillinase, including methicillin-resistant strains, Enterococci, Streptococcus pyogenes and Diplococcus pneumoniae). Amikacin is not degraded by most enzymes inactivating other aminoglycosides, therefore microorganisms resistant to gentamicin, tobramycin and kanamycin are susceptible to amikacin. PIERAMI is therefore indicated in short treatments of severe infections caused by strains which are susceptible; namely: bacteriemia and septicemia (including neonatal sepsis); complicated and recurrent infections of the genito-urinary tracts; infections of the respiratory tract, of the osteoarticular apparatus, of the central nervous system (including meningitis); infections of the gastrointestinal tract (including peritonitis); burns and post-operative infections. PIERAMI can be used as the antibiotic of first choice in suspected Gram-negative infections, even before obtaining results of microbiological analysis. PIERAMI is quickly absorbed after parenteral administration, and bactericidal serum concentrations are maintained for 10-12 hours.

DOSAGE AND ADMINISTRATION

Intramuscular and intravenous administration. In non complicated infections caused by germs susceptible to amikacin, recommended dosage should be effective within 24-48 hours. If no clinical change occur within 3-5 days, an alternative therapy should be considered on the basis of the microbiological tests. **Adults and children:** 15 mg/kg/day (7,5 mg/kg administered every 12 hours). In severe cases and in infections caused by Pseudomonas: 15 mg/kg/day (5 mg/kg administered every 8 hours). **Premature and full term neonates:** initial attack dose: 10 mg/kg; continue with 7,5 mg/kg every 12 hours. **Life-Threatening infections, and/or caused by Pseudomonas:** in **adults**, dose can be increased to 500 mg every 8 hours, **but** the dose of 1,5 g/day must never be exceeded, and the treatment must not be prolonged for more than 10 days. Maximum total dose is 15 g. **Infections of the urinary tract (excluding infections caused by Pseudomonas):** 7,5 mg/kg/day (3,75 mg/kg administered every 12 hours). **Impaired renal function:** in patients with impaired renal function, in order to avoid accumulation phenomena, dosage should be reduced or intervals between administration should be increased. I.m. administration is the preferred route, but, if necessary, i.v. administration can be used by infusion over a short period with identical dosage schedule and using a quantity of liquid sufficient for 30-60 minutes. For intravenous infusion, the suitable diluents are the following: saline, 5% glucose in water, Ringer lactate solution.

CONTRA-INDICATIONS, WARNINGS

Hypersensitivity to amikacin as well as to other aminoglycosides. Patients treated with aminoglycosides should be under close clinical observation because of potential ototoxicity and nephrotoxicity related to their use. Ototoxicity, both vestibular and auditory, can occur in patients treated with high doses or for longer periods than those recommended; ototoxicity risk induced by amikacin is higher in patients with pre-existing renal damage. Hearing loss at high frequencies occurs usually first and can be demonstrated by audiometric tests only; vertigo can occur because of vestibular insult. Potential ototoxicity in children is not reported. In default of further data, amikacin should be used in children only in cases in which another aminoglycoside is not indicated, and under close clinical observation. Aminoglycosides are potentially nephrotoxic. Monitoring of renal function is recommended during therapy for patients with known or suspected renal impairment, and also in patients with symptoms of reduced renal function during the treatment (decreased creatinine clearance, presence of cells in the urine, oliguria, proteinuria, urine decreased specific gravity, increased nitrogen retention). Evidence of nephrotoxicity or ototoxicity requires discontinuation of the treatment or a dosage adjustment. Serum concentrations of the antibiotic should be monitored when feasible, and concentrations exceeding 35 mcg/ml should be avoided. Concurrent use of other neurotoxic or nephrotoxic antibiotics, such as kanamycin, gentamicin, tobramycin, neomycin, streptomycin, cephaloridin, paromomycin, viomycin, polimixin B, colistin and vancomycin, should be avoided. PIERAMI should not be administered concurrently with potent diuretics, such as: etacrinic acid, furosemide and mannitol, because of the possibility of a quick hearing loss. IN PREGNANT WOMEN AND IN VERY EARLY INFANCY, THE PRODUCT SHOULD BE ADMINISTERED IN CASES OF REAL NECESSITY ONLY AND UNDER CLOSE CLINICAL OBSERVATION. Since neuromuscular blockade has been reported in animals receiving high doses of amikacin, the possibility of neuromuscular blockade and of respiratory paralysis in the concomitant administration of PIERAMI with anesthetics or neuromuscular-blocking agents should be kept in mind. When concomitant administration of amikacin with another antibiotic is indicated (mixed infections or superinfections), mixing of such drugs in the syringes or in infusion bottles should be avoided. KEEP OUT OF REACH OF CHILDREN.

HAW SUPPLIED

Vials of 2 ml containing amikacin sulfate equivalent to 100-250-500 mg of amikacin.
Boxes of 1.
ALL THE ABOVE CONCENTRATIONS CAN BE SUPPLIED IN HOSPITAL BOXES.