MIACIN®

Amikacin

ACTION

Miacin is a semi-synthetic aminoglycoside antibiotic. Miacin is rapidly absorbed after intramuscular administration. Tolerance studies in normal volunteers reveal that Amikacin is well tolerated locally following repeated intramuscular dosing, and when given at maximally recommended doses, no ototoxicity or nephrotoxicity has been reported. Amikacin is excreted primarily by glomerular filtration. Following administration at the recommended dose, therapeutic levels are found in bone, heart, gall bladder and lung tissue in addition to significant concentrations in urine, bile, sputum, bronchial secretions, interstitial, pleural and synovial fluids.

INDICATIONS

Miacin is active against the following gram-negative and gram-positive bacteria: Pseudomonas species, Escherichia coli, Proteus species (indole-positive and indole-negative), Providencia species, Klebsiella Enterobacter,Serratia species, Acinetobacter species, Citrobacter freundii, penicillinase and nonpenicillinase producing Staphylococcus species including methicillin resistant strains.

Miacin in indicated in the short term treatment of serious infections such as:

- Bacterial septicaemia (including neonatal sepsis)
- Respiratory tract infections
- Bones and joints infections
- Central nervous system infections (including meningitis)
- Skin and soft tissue infections
- Intra-abdominal infections (including peritonitis)
- Burns and post-operative infections (including post-vascular surgery)
- Urinary tract infection.

DOSAGE AND ADMINISTRATIONS

Miacin can be used intramuscularly and intravenously. The recommended dosage for adults , children and infants with normal renal function is 15 mg/kg/day divided into 2 or 3 equal doses administered at equally divided intervals.

Treatment of patients in the heavier weight classes should not exceed 1.5g/day. When Miacin is indicated in newborns, it is recommended that a loading dose of 10 mg/kg be administered initially to be followed with 7.5 mg/kg every 12 hours.

The solution for intravenous use is prepared by adding the contents of a 500 mg ampoules to 100-200 ml of sterile diluent such as 5% dextrose injection, 5% dextrose and 0.2% sodium chloride injection, and 0.45% sodium chloride injection, 0.9% sodium chloride injection, lactated Ringer's injection.

Amikacin is stable for 24 hours at room temperature at concentrations of 0.25 and 5 mg/ml in the above solutions.

The solution is administered to adults over a 30-60 minute period. In pediatric patients the amount of fluid used will depend on the amount ordered for the patients. it should be a sufficient amount to infuse the amikacin over 30-60 minute period. Infants should receive a 1-2 hour infusion. Amikacin should not be physically premixed with other drugs but should be administered separately.

Renal impairment: Dosage should be adjusted in patients with impaired

renal function.

CONTRAINDICATIONS

A history of hypersensitivity or serious toxic reactions to aminoglycosides.

WARNING

Patients treated with parenteral aminoglycosides should be under close clinical observation because of the potential ototoxicity and nephrotoxicity associated with their use. The risk of ototoxicity and nephrotoxicity is greater in patients with impaired renal function and in those who receive high doses or prolonged therapy.

PRECAUTIONS

Amikacin is potentially nephrotoxic, ototoxic and neurotoxic. The concurrent or serial use of either ototoxic or nephrototoxic agents should be avoided either systemically or topically because of the potential for additive effects. Since Amikacin is present in high concentrations in the renal excretory system, patients should be well hydrated to minimise chemical irritation of the renal tubules.

Pregnancy: There are no well controlled studies in pregnant women, but investigation experience does not include any positive evidence of adverse effects to the fetus. If this drug is used during nursing, the patients should be made wether to discontinue nursing or to discontinue the drug.

SIDE EFFECTS

All aminoglycosides have the potential to induce auditory, vestibular and renal toxicity and neuromuscular blockade. Other adverse reactions which have been reported on rare occasion are: skin rash, drug fever, headache, nausea and vomiting.

OVERDOSAGE

In the event of overdosage or toxic reaction, peritoneal dialysis or hemodialysis will aid in the removal of Amikacin from the blood.
In the newborn infant, exchange transfusion may also be considered.

PRESENTATION

Ampoules

MIACIN 100 Amikacin (as sulfate) 100 mg/2 ml
MIACIN 500 Amikacin (as sulfate) 500 mg/2 ml

THIS IS A MEDICAMENT

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Follow the doctor's prescription strictly, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

HIKMA

Keep medicament out of the reach of children

Hikma Pharmaceuticals