For the use of a Registered Medical Practitioner or a Hospital or a Laboratory

℞ Amikacin Injection IP 100 mg / 2 ml

AMERICAN

Amixin 100
Injection

Composition:
Each 2 ml contains:

Amikacin Sulphate IP Eq. to Amikacin	100 mg
Methyl Paraben IP (As Preservative)	0.18% w/v
Propyl Paraben IP (As Preservative)	0.02% w/v
Water for Injections IP	q.s.

For IM/IV Use Only

Therapeutic indications
Amikacin Injection is a semi-synthetic, aminoglycoside antibiotic which is active against a broad spectrum of Gram-negative organisms, including *Pseudomonas sp* and some Gram-positive *organisms*.
Amikacin is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including *Pseudomonas sp* species. Although amikacin is not the drug of choice for infections due to staphylococci, at times it may be indicated for the treatment of known or suspected staphylococcal disease. These situations include: the initiation of therapy for severe infections when the *organisms*. suspected are either Gram-negative or staphylococci, patients allergic to other antibiotics, and mixed staphylococcal/Gram-negative infections.

Posology and method of administration
Amikacin should not be physically premixed with other drugs, but should be administered separately according to the recommended dose and route.

The patient's pre-treatment bodyweight should be obtained for calculation of correct dosage.
The status of renal function should be estimated by measurement of the serum creatinine concentration or calculation of the endogenous creatinine clearance rate. The blood urea nitrogen (BUN) is much less reliable for this purpose. Reassessment of renal function should be made periodically during therapy.
Adults and Children over 12 years

The recommended intramuscular or intravenous dosage for adults and adolescents with normal renal function (creatinine clearance ≥50 ml/min) is 15 mg/kg/day which may be administered as a single daily dose or divided into 2 equal doses i.e. 7.5 mg/kg 12 h. The total daily dose should not exceed 1.5 g. In endocarditis and in febrile neutropenic patients, dosing should be twice daily, as there is not enough data to support once daily dosing.
Children 4 weeks to 12 years

The recommended intramuscular or intravenous (slow intravenous infusion) dose in children with normal renal function is 15-20 mg/kg/day which may be administered as 15-20 mg/kg, once a day; or as 7.5 mg/kg 12 h. In endocarditis and in febrile neutropenic patients dosing should be twice daily, as there is not enough data to support once daily dosing.
Neonates

An initial loading dose of 10 mg/kg followed by 7.5 mg/kg q 12 h.
Method of administration:
Amikacin sulfate injection may be given intramuscularly or intravenously.
Pharmacological properties
ATC code: J01G B06

Pharmacodynamic Properties
Amikacin is a semi-synthetic aminoglycoside antibiotic derived from Kanamycin A. It is active against a broad spectrum of Gram-negative organisms, including *Pseudomonas sp, Escherichia coli* and some Gram-positive organisms, e.g. *Staphylococcus aureus.*
Aminoglycoside antibiotics are bactericidal in action. Although the exact mechanism of action has not been fully elucidated, the drugs appear to inhibit protein synthesis in susceptible bacteria by irreversibly binding to 30S ribosomal subunits.

Pharmacokinetic Properties
Amikacin is rapidly absorbed after intramuscular injection. Peak plasma concentrations equivalent to about 20 mg / mL are achieved one hour after IM doses of 500 mg, reducing to about 2 µg / mL 10 hours after injections.
Twenty per cent or less is bound to serum protein and serum concentrations remain in the bactericidal range for sensitive *organisms* for 10 to 12 hours.

Single doses of 500 mg administered as an intravenous infusion over a period of 30 minutes produce a mean peak serum concentration of 38 µg / mL. Repeated infusions do not produce drug accumulation in adults with normal renal function. However, decreased renal function will lead to accumulation.

In adults with normal renal function the plasma elimination half-life of amikacin is usually 2-3 hours. 94 - 98% of a single IM or IV dose of amikacin is excreted unchanged by glomerular filtration within 24 hours. Urine concentrations of amikacin average 563 µg / mL. in the first 6 hours following a single 250 mg IM dose and 163 µg / mL. over 6-12 hours. Following a single 500 mg IM dose urine concentrations average 832 µg / mL. in adults with normal renal function.

Amikacin diffuses readily through extracellular fluids and is excreted in the urine unchanged, primarily by glomerular filtration. It has been found in pleural fluid, amniotic fluid and in the peritoneal cavity following parenteral administration.
Contraindications
Amikacin sulphate injection is contraindicated in patients with known allergy to amikacin or any component of the formulation.
Special warning and precautions for use
Patients should be well hydrated during amikacin therapy.

Caution should be applied to patients with pre-existing renal insufficiency, pre-existing hearing or vestibular damage and diminished glomerular filtration. Patients treated with parenteral aminoglycosides should be under close clinical observation because of the potential ototoxicity and nephrotoxicity associated with their use. Safety for treatment periods which are longer than 14 days has not been established.
If therapy is expected to last seven days or more in patients with renal impairment, or 10 days in other patients, a pre-treatment audiogram should be obtained and repeated during therapy.
Undesirable effects
When the recommended precautions and dosages are followed the incidence of toxic reactions, such as tinnitis, vertigo, and partial reversible deafness, skin rash, drug fever, headache, paraesthesia, nausea and vomiting is low. Urinary signs of renal irritation (albumin, casts, and red or white cells), azotaemia and oliguria have been reported.
Overdose
In case of overdosage there is a general risk for nephro-, oto- and neurotoxic (neuromuscular blockage) reactions. Neuromuscular blockage with respiratory arrest needs appropriate treatment including application of ionic calcium (e.g. as gluconat or lactobionat in 10-20% solution). In the event of overdosage or toxic reaction, peritoneal dialysis or haemodialysis will aid in the removal of amikacin from the blood. Amikacin levels are also reduced during continuous arteriovenous hemofiltration. In the newborn infant, exchange transfusion may also be considered.
Interaction with other medicinal products and other forms of interactions
The concurrent or serial use of other neurotoxic, ototoxic or nephrotoxic agents, particularly bacitracin, cisplatin, amphotericin B, ciclosporin, tacrolimus, cephaloridine, paromomycin, viomycin, polymyxin B, colistin, vancomycin, or other aminoglycosides should be avoided either systemically or topically because of the potential for additive effects. Where this is not possible, monitor carefully.
Increased nephrotoxicity has been reported following concomitant parenteral administration of aminoglycoside antibiotics and cephalosporins. Concomitant cephalosporin use may spuriously elevate creatinine serum level determinations.
The concurrent use of amikacin sulfate injection with potent diuretics (ethacrynic acid or furosemide) should be avoided since diuretics by themselves may cause ototoxicity. In addition, when administered intravenously, diuretics may enhance aminoglycoside toxicity by altering antibiotic concentrations in serum and tissue.

Pregnancy & Lactation:
Use with Caution.

Storage: Store at a temperature not exceeding 30°C. Protect from light.

Keep the medicine out of reach children.

Presentation
2ml vial packed in the carton along with package insert.

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