Amistar™ IM/IV Injection

Amikacin Sulfate USP

Composition

Amistar™ 100 IM/IV Injection: Each 2 ml ampoule contains Amikacin 100 mg as Amikacin Sulfate USP.

Amistar™ 500 IM/IV Injection: Each 2 ml ampoule contains Amikacin 500 mg as Amikacin Sulfate USP.

Indication

Amikacin (**Amistar™**) is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria. Amikacin 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 postoperative infections (including postvascular surgery). Clinical studies have shown Amikacin also to be effective in serious complicated and recurrent urinary tract infections due to those organisms.

Amikacin was effective in infections caused by gentamicin and/or tobramycin-resistant strains of Gram-negative organisms, particularly Proteus rettgeri, Providencia stuartii, Serratia marcescens, and Pseudomonas aeruginosa.

Amikacin has also been shown to be effective in staphylococci infections and may be considered as initial therapy under certain conditions in the treatment of known or suspected staphylococcal disease such as, severe infections where the causative organism may be either a Gram-negative bacterium or a staphylococcus.

Dosage and Administration

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

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

Elderly: Amikacin is excreted by the renal route. Renal function should be assessed whenever possible and dosage adjusted as described under impaired renal function.

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 1.5g/day nor be administered for a period longer than 10 days. A maximum total adult dose of 15g should not be exceeded.

Urinary tract infections: (other than pseudomonal infections): 7.5mg/kg/day in two equally divided doses (equivalent to 250 mg b.i.d. in adults).

Impaired renal function: In patients with impaired renal function, the daily dose should be reduced and/or the intervals between doses increased to avoid accumulation of the drug.

Route of administration

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

Intraperitoneal use

Amikacin may be used as an irrigant after recovery from anaesthesia in concentrations of 0.25% (2.5 mg/ml).

Pediatric Use

Safety and effectiveness of Amikacin for injection in children or adolescents under 16 years have not been established.

Side Effects

The adverse effects have been reported with the use of Amikacin are tinnitus, vertigo, partial reversible or irreversible deafness, skin rash, drug fever, headache, paraesthesia, nausea and vomiting.

Contraindications

Amikacin Injection is contraindicated in patients with a known history of hypersensitivity to Amikacin, any constituents of the injection.

Overdose

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

Use in Pregnancy and Lactation

Amikacin rapidly crosses the placenta into the foetal circulation and amniotic fluid and there is a potential risk of ototoxicity in the foetus. There is no information available regarding the safety of this drug during breastfeeding.

How Supplied

Amistar™ 100 IM/IV Injection: Each box contains 10 ampoules in Alu-PVC blister pack.
Amistar™ 500 IM/IV Injection: Each box contains 10 ampoules in Alu-PVC blister pack.

Manufactured by:

SQUARE
PHARMACEUTICALS LTD.
BANGLADESH