

# PSUDONIL

Amikacin Sulfate USP Injection

**Composition : Psudonil-100 Injection (IV/IM) :** Each Ampoule contains Amikacin 100mg as Amikacin Sulfate USP.

**Psudonil-250 Injection (IV/IM) :** Each Ampoule contains Amikacin 250mg as Amikacin Sulfate USP.

**Psudonil-500 Injection (IV/IM) :** Each Ampoule contains Amikacin 500mg as Amikacin Sulfate USP.

**Pharmacology :** Amikacin Sulfate is semi synthetic aminoglycoside antibiotic derived from kanamycin. Amikacin is rapidly absorbed after intramuscular injection. Peak serum levels are approximately 11mg/L and 23mg/L are reached one hour after i.m. dose of 250mg and 500mg respectively. Amikacin diffuses readily through extracellular fluids and is excreted in the urine unchanged, primarily by glomerular filtration. Half-life in individuals with normal renal functions is two to three hours.

**Indications:** Amikacin is indicated in the short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria. It 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 Gram-negative organisms. It 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 Gentamycin and/or Tobramycin resistant strains of Gram-negative organisms. Amikacin has also been shown to be effective in *Staphylococcal* infection and may be considered as initial therapy under certain condition in the treatment of known suspected *Staphylococcal* disease such as, severe infections where the causative organism may either a Gram-negative bacterium or *Staphylococcus* due to susceptible strains of *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 organism such as *streptococci* or *pneumococci*.

**Dosages and Administration :** Serious infection caused by susceptible organisms: Adults & Children: 15mg/kg/day in two equally divided doses every 8 to 12 hours IM or IV (if IV, diluted in 100 or 200 ml infusion solution or normal saline given over 30 to 60 minutes). Life threatening infections and/or those caused by *Pseudomonas* bacteria: The adult dose may be increased maximum 500 mg every 8 hours but neither exceed 1.5g/day nor be administered for a period longer than 10 days. A maximum total adult dose of 15gm should not be exceeded. Neonates with normal renal function: Initially loading 10 mg/kg daily divided dosage by IM or IV (if given by IV an infusion period of 1 to 2 hours recommended) then 7.5 mg/kg/day every 18 to 24 hours. UTI (other than *Pseudomonas* infections): Adults : 7.5mg/kg/day in two equally divided doses (eqv. to 250 mg b.i.d.). Or, as directed by the registered physician.

**Contraindications :** A history of hypersensitivity to Amikacin or any other aminoglycoside is contraindicated for its use.

**Precautions :** Aminoglycosides are quickly and almost totally absorbed when they are applied topically, except to the urinary bladder, in association with surgical procedures. Irreversible deafness, renal failure death due to neuromuscular blockade have been reported following irrigation of both small and large surgical fields with an aminoglycoside preparation.

**Side effects :** All aminoglycosides have the potential to induce auditory, vestibular and renal toxicity and neuromuscular blockade.

**Use In Pregnancy & Lactation :** Psudonil can cause fetal harm when administered to a pregnant woman. It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

**Storage :** Store below 30<sup>o</sup> C in a dry place.

**Packing : Psudonil-100 Injection (IV/IM) :** Each box contains 1 x 5 ampoules in a blister pack.

**Psudonil-250 Injection (IV/IM) :** Each box contains 1 x 5 ampoules in a blister pack.

**Psudonil-500 Injection (IV/IM) :** Each box contains 1 x 5 ampoules in a blister pack.



Manufactured by  
**DRUG INTERNATIONAL LTD.**  
Tongi, Gazipur, Bangladesh