

Brand Name: AMIREKA 500

Composition: Amikacin Sulphate injection I.P.

Dosage Form: Injection

Category: Antibiotic – Aminoglycoside

Packaging Type: VIAL

Packaging: 500 mg / 2 ml

Brief Product Information:

AMIREKA 500 is a sterile antibiotic injection manufactured by **AstraEureka Pharmaceuticals**, a trusted manufacturer of composition containing Amikacin Sulphate I.P. equivalent to 500 mg of Amikacin per 2 ml. It is used to treat serious bacterial infections, including infections of the respiratory tract, urinary tract, bones, joints, abdomen, and bloodstream, especially when caused by gram-negative organisms. Amikacin, an aminoglycoside antibiotic, works by inhibiting bacterial protein synthesis, leading to bacterial cell death. The formulation also includes Methyl Paraben and Propyl Paraben as preservatives.

Composition:

Each 2 ml contains:

Amikacin Sulphate I.P.

equivalent to Amikacin.....500 mg

Methyl Paraben I.P..... 0.18% w/v

Propyl Paraben I.P.....0.02%w/v.

Key Ingredients:

- Amikacin Sulphate I.P. (500 mg equivalent).
- Methyl Paraben I.P. 0.18% w/v.
- Propyl Paraben I.P. 0.02%w/v.

Key Benefits:

1. Broad-spectrum activity against resistant gram-negative bacteria
2. Effective in severe infections where other antibiotics may fail
3. Rapid bactericidal action
4. Can be used in combination with other antibiotics for synergistic effect

Indications:

1. Respiratory tract infections
2. Urinary tract infections
3. Intra-abdominal infections

4. Bloodstream infections (sepsis)
5. Bone and joint infections
6. Post-operative and hospital-acquired infections

Directions for Use:

1. Administered by intramuscular or intravenous injection
2. To be given by a trained healthcare professional only
3. Reconstitute if required and use aseptic technique

Doses and Administration:

1. Adults: 15 mg/kg/day in 2–3 divided doses
 - Dose adjusted in renal impairment based on creatinine clearance
 - Duration and frequency as prescribed by the physician

Safety Information:

1. Monitor kidney function during prolonged therapy
2. Audiometry monitoring advised in long-term or high-dose therapy
3. Use with caution in elderly or dehydrated patients
4. Avoid mixing with other drugs in the same syringe

Mechanism of Action:

- Amikacin binds to the 30S ribosomal subunit of bacteria, disrupting mRNA translation and inhibiting protein synthesis.
- This leads to faulty bacterial proteins and cell death. It is particularly effective against gram-negative organisms, including *Pseudomonas*, *E. coli*, and *Klebsiella*.

Contraindications:

1. Hypersensitivity to aminoglycosides
2. Known auditory or vestibular toxicity
3. Myasthenia gravis
4. Severe renal impairment without dose adjustment

Side Effects:

1. Nephrotoxicity (kidney damage)
2. Ototoxicity (hearing loss, tinnitus, vertigo)
3. Injection site reactions

4. Headache, rash, or nausea (rare)

Important Notice:

- Not for self-administration
- Dosage must be individualized and monitored
- Avoid concurrent use with other ototoxic or nephrotoxic drugs

Storage Condition:

1. Store below 25°C
2. Protect from light and heat
3. Do not freeze
4. Keep out of reach of children

Packing Information:

- Each vial contains 2 ml (500 mg) of Amikacin Injection
- Available in sealed sterile vials for hospital and clinical use

