

Mikaxyle 250 Injection

Amikacin (250 mg) Injection

Description:

Amikacin is a broad-spectrum aminoglycoside antibiotic used to treat serious bacterial infections. It works by inhibiting bacterial protein synthesis, effectively stopping bacterial growth and replication. This injection is commonly used to combat infections caused by Gram-negative bacteria and some Gram-positive bacteria.

Composition (Per 2 ml Vial/Injection):

- Amikacin (as Amikacin Sulfate): 250 mg
 - Excipients: q.s.
 - Solvent: Sterile water for injection.
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Indications:

Amikacin is indicated for the treatment of:

1. **Respiratory Tract Infections:** Pneumonia, bronchitis, and infections secondary to mechanical ventilation.
 2. **Urinary Tract Infections:** Complicated and uncomplicated UTIs, including pyelonephritis.
 3. **Skin and Soft Tissue Infections:** Abscesses, cellulitis, and infected wounds.
 4. **Intra-abdominal Infections:** Peritonitis, appendicitis, and abdominal abscesses.
 5. **Sepsis and Bacteremia:** Bloodstream infections caused by susceptible bacteria.
 6. **Bone and Joint Infections:** Osteomyelitis and septic arthritis.
 7. **CNS Infections:** Meningitis (used with other agents for synergy).
 8. **Post-operative Infections:** Post-surgical wound and nosocomial infections.
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Dosage and Administration:

Route of Administration:

- Administered intravenously (IV) or intramuscularly (IM).

Dosage Guidelines:

- **Adults:**
 - 15 mg/kg/day in divided doses (every 8–12 hours).
 - Maximum daily dose: 1.5 g.
- **Children:**
 - 15–20 mg/kg/day in divided doses (every 8–12 hours).
- **Neonates:**
 - 10 mg/kg as a loading dose, followed by 7.5 mg/kg every 12 hours.
- **Renal Impairment:**
 - Dosage must be adjusted according to the degree of renal dysfunction to prevent accumulation and toxicity.

Duration of Therapy:

- Treatment duration is typically 7–10 days, depending on the infection's severity and clinical response.
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Contraindications:

- Known hypersensitivity to Amikacin, aminoglycosides, or any component of the formulation.
 - Severe renal impairment without dosage adjustments.
 - Pregnancy: Should be avoided unless necessary due to potential fetal harm (Category D).
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Warnings and Precautions:

1. **Nephrotoxicity:**
 - Amikacin can impair kidney function. Regular monitoring of renal

parameters (serum creatinine, BUN) is essential, especially in high-risk patients.

2. Ototoxicity:

- May cause irreversible damage to hearing or balance. Monitor for symptoms like tinnitus, hearing loss, or vertigo.

3. Neuromuscular Blockade:

- Can worsen symptoms in patients with neuromuscular disorders such as myasthenia gravis.

4. Electrolyte Imbalance:

- Monitor levels of magnesium, calcium, and potassium during prolonged therapy.

5. Concurrent Use of Other Nephrotoxic or Ototoxic Drugs:

- Avoid using with medications like vancomycin, cisplatin, or loop diuretics unless necessary.

6. Prolonged Use:

- Long-term use may lead to bacterial resistance or secondary infections (e.g., fungal overgrowth).

- Enhanced risk of hearing damage when combined with loop diuretics like furosemide.

• Neuromuscular Blocking Agents:

- Potentiation of muscle relaxation effects when co-administered with agents like succinylcholine or pancuronium.

Storage Instructions:

- Store at room temperature, between 15°C to 25°C (59°F to 77°F).
- Protect from light and excessive heat.
- Keep out of reach of children.
- Do not freeze.

Note:

Amikacin is a prescription medication and should be used strictly under the supervision of a healthcare provider.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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Panchkula-134113

TM: Trademark Applied for

Side Effects:

- **Common Side Effects:**
 - Pain or redness at the injection site
 - Nausea or vomiting
 - Mild headache
- **Serious Side Effects:**
 - **Nephrotoxicity:** Elevated creatinine or reduced urine output
 - **Ototoxicity:** Hearing loss, vertigo, or tinnitus
 - **Allergic Reactions:** Rash, pruritus, swelling, or anaphylaxis
 - **Neuromuscular Blockade:** Respiratory depression in rare cases

Drug Interactions:

- **Nephrotoxic Agents:**
 - Increased risk of kidney damage when used with vancomycin, amphotericin B, or NSAIDs.
- **Ototoxic Drugs:**