

Mikaxyle 100 Injection

Amikacin (100 mg) Injection

Description:

Amikacin is a broad-spectrum aminoglycoside antibiotic used to treat serious bacterial infections. This injectable formulation contains Amikacin, which works by inhibiting bacterial protein synthesis, thereby stopping the growth of bacteria. It is commonly used to treat infections caused by Gram-negative and some Gram-positive bacteria, particularly in patients who are hospitalized or critically ill.

Composition (Per 2 ml Vial/Injection):

- **Amikacin (as Amikacin Sulfate): 100 mg**
 - **Excipients: q.s. to make up 2 ml of solution**
 - **Solvent: Sterile water for injection**
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Indications:

- **Bacterial Infections:**
Amikacin is used to treat infections caused by Gram-negative and Gram-positive bacteria, including but not limited to:
 - Respiratory tract infections (pneumonia, bronchitis)
 - Urinary tract infections
 - Bloodstream infections (bacteremia and septicemia)
 - Skin and soft tissue infections
 - Abdominal infections (peritonitis)
 - Bone and joint infections
 - Meningitis
 - Intra-abdominal infections
 - Post-surgical infections
 - **Infection in Immunocompromised Patients:**
 - For patients with weakened immune systems, such as those undergoing chemotherapy or organ transplantation.
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Dosage and Administration:

- **Adults:**
 - The usual dosage is 15 mg/kg body weight per day, divided into 2 to 3 doses. The maximum dose should not exceed 1.5 g/day.
 - The dose is usually administered by intravenous (IV) infusion over 30 minutes to 1 hour, or by intramuscular (IM) injection.
 - **Renal Impairment:**
 - In patients with renal dysfunction, dosage adjustments are required to prevent accumulation of the drug, as Amikacin is primarily eliminated by the kidneys.
 - **Pediatric Use:**
 - Pediatric dosing is generally based on body weight. It is advised to consult a healthcare provider for age-specific dosages.
 - **Duration of Therapy:**
 - Duration varies depending on the type and severity of the infection. Typically, treatment lasts for 7 to 10 days.
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Contraindications:

- **Hypersensitivity to Amikacin, aminoglycosides, or any of the ingredients in the formulation.**
 - **Severe renal impairment:** Use with caution in patients with renal insufficiency.
 - **Pregnancy:**
 - **Category D:** Amikacin should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus.
 - **Lactation:**
 - Amikacin is excreted in breast milk, so it should be used cautiously in breastfeeding women.
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Warnings and Precautions:

- **Nephrotoxicity:**
 - Amikacin can cause kidney damage, especially with prolonged use or high doses. Monitor kidney function regularly, especially in high-risk patients (elderly, pre-existing kidney disease, or those on other nephrotoxic drugs).
- **Ototoxicity:**
 - Amikacin may cause damage to the hearing (auditory) and balance (vestibular) functions. Audiometric testing is recommended during prolonged therapy.
- **Electrolyte Imbalance:**
 - Amikacin may cause electrolyte disturbances (especially low levels of magnesium and calcium), so electrolyte levels should be monitored during treatment.
- **Concurrent use with other nephrotoxic or ototoxic drugs:**
 - Caution should be exercised when used alongside other drugs that can harm the kidneys or ears (e.g., vancomycin, cisplatin, loop diuretics).
- **Myasthenia Gravis:**
 - Amikacin can worsen the symptoms of myasthenia gravis and other neuromuscular disorders.

Side Effects:

- **Common Side Effects:**
 - Injection site reactions (pain, redness, swelling)
 - Nausea or vomiting
 - Elevated liver enzymes
 - Rash
- **Serious Side Effects:**
 - Nephrotoxicity (kidney damage), especially in patients with renal insufficiency
 - Ototoxicity (hearing loss or dizziness)
 - Allergic reactions (anaphylaxis, angioedema, swelling of the throat or face)
 - Severe gastrointestinal effects (diarrhea, blood in stools)
 - Respiratory depression (in severe overdose)

Drug Interactions:

- **Other Nephrotoxic Agents:**
 - Caution when using alongside other nephrotoxic drugs, such as cisplatin, cyclosporine, or diuretics.
- **Other Ototoxic Agents:**
 - Use with caution when combined with loop diuretics (e.g., furosemide) or other ototoxic drugs.
- **Muscle Relaxants:**
 - May enhance the effects of neuromuscular blocking agents (e.g., curare-type drugs), leading to respiratory depression.

Storage:

- **Before opening:** Store the vial at room temperature, between 15°C to 25°C (59°F to 77°F).
- **After preparation:** The prepared solution should be used immediately. If not used, discard any unused portion.
- **Keep the vial tightly closed, and out of reach of children.**
- **Do not freeze the injection.**

Note:

Amikacin is a potent antibiotic that should only be used under the supervision of a healthcare provider. Always complete the prescribed course of therapy, even if symptoms improve.

Manufactured in India for:

CafoliTM
L I F E C A R E

Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

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