

Information For the User
Amikacin (250mg) Injection

Mikatyle 250 Injection

Brand Name: Mikatyle 250 Injection

Composition:

Each 2 mL vial contains:
Amikacin Sulphate IP equivalent to Amikacin 250 mg
Water for Injection IP q.s.

Dosage Form:

Sterile solution for intramuscular (IM) or intravenous (IV) use

Therapeutic Indication:

Indicated for the treatment of serious bacterial infections caused by susceptible gram-negative and selected gram-positive organisms
Used in infections of the respiratory tract urinary tract gastrointestinal tract bones joints skin soft tissue and in septicemia
Also indicated in post-surgical infections hospital-acquired infections and pelvic inflammatory disease

Mechanism of Action:

Amikacin is a semi-synthetic aminoglycoside antibiotic
It binds irreversibly to the 30S ribosomal subunit of bacteria inhibiting protein synthesis and causing bacterial cell death
It is bactericidal and effective against a wide range of aerobic gram-negative bacilli including resistant strains

Dosage & Administration:

Adults: 15 mg/kg/day in 2 equally divided doses (7.5 mg/kg every 12 hours)
Children: 15–20 mg/kg/day in 2–3 divided doses
Neonates: 10 mg/kg initially followed by 7.5 mg/kg every 12 hours
Administer deep IM or by slow IV infusion over 30 to 60 minutes
Adjust dose based on renal function and severity of infection

Contraindications:

Hypersensitivity to Amikacin or other aminoglycosides
Myasthenia gravis
History of auditory or vestibular nerve damage

Warnings & Precautions:

Monitor renal function auditory function and serum Amikacin levels during prolonged therapy
Use with caution in patients with renal impairment elderly and dehydrated individuals
Avoid concurrent use with other nephrotoxic or ototoxic agents
Discontinue if signs of toxicity appear

Side Effects:

Common: pain at injection site headache nausea

Less common: nephrotoxicity ototoxicity vertigo rash
Rare: anaphylaxis neuromuscular blockade

Storage:

Store below 25°C

Protect from light

Do not freeze

Use immediately after opening and discard unused portion

Packaging:

Mikatyle 250 Injection is available in 2 mL sterile glass ampoules or vials

Schedule:

Schedule H Prescription Drug – To be sold by retail on the prescription of a registered medical practitioner only

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.

(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,
Panchkula-134113

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