

Information For the User
Amikacin (100mg) Injection

Mikatyle 100 Injection

Brand Name: Mikatyle 100 Injection

Composition:

Each mL contains:

Amikacin Sulphate IP equivalent to Amikacin 100 mg

Water for Injection IP q.s.

Dosage Form:

Parenteral preparation for intramuscular (IM) or intravenous (IV) use

Therapeutic Indication:

Indicated for the treatment of serious bacterial infections caused by susceptible gram-negative and some gram-positive organisms

Effective in infections of the respiratory tract urinary tract abdomen skin bones joints and in septicemia

Also used in post-operative infections and hospital-acquired infections

Mechanism of Action:

Amikacin is an aminoglycoside antibiotic that binds to the 30S ribosomal subunit of bacteria

It inhibits protein synthesis resulting in bacterial cell death

It is bactericidal and active against a broad spectrum of aerobic gram-negative bacilli including multi-drug resistant strains

Dosage & Administration:

Adults: 15 mg/kg/day in divided doses every 8 or 12 hours depending on severity of infection and renal function

Children: 15–20 mg/kg/day in 2–3 divided doses

Neonates: initial dose of 10 mg/kg followed by 7.5 mg/kg every 12 hours

Administer by deep IM injection or slow IV infusion over 30 to 60 minutes

Adjust dose in renal impairment based on creatinine clearance

Contraindications:

Hypersensitivity to Amikacin or other aminoglycosides

Myasthenia gravis

Pre-existing auditory or vestibular nerve damage

Warnings & Precautions:

Use with caution in elderly patients and those with renal impairment

Monitor renal function serum drug levels and auditory function during prolonged therapy

Avoid concurrent use with other ototoxic or nephrotoxic drugs

Prolonged use may lead to superinfection with resistant organisms

Side Effects:

Common: pain at injection site nausea headache

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

Storage:

Store below 25°C

Protect from light and do not freeze

Use immediately after opening and discard unused portion

Packaging:

Mikatile 100 Injection is available in 2 mL 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

TM: Trademark Applied for