

Nafithromycin: Pioneering India's Indigenous Antibiotic Revolution

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Nafithromycin is a novel antibiotic derived from *Streptomyces* species, showing potent activity against antibiotic-resistant bacteria. India's development of Nafithromycin, the first indigenous macrolide antibiotic, is indeed a significant milestone in the global fight against antimicrobial resistance (AMR). This achievement not only underscores the nation's growing expertise in pharmaceutical research and innovation but also provides a ray of hope for combating resistant bacterial infections.^[1]

Nafithromycin is a novel fourth-generation semi-synthetic macrolide, classified as a ketolide, with a unique naphthyl group that inhibits peptidoglycan biosynthesis and bacterial protein synthesis by targeting the 50S subunit of the 70S ribosome. Designed to overcome bacterial resistance, it features a keto function at C3, replacing the L-cladinose sugar, which broadens its spectrum of activity.^[2] Nafithromycin is highly effective against Gram-positive bacteria such as Methicillin Resistant *Staphylococcus Aureus* (MRSA) and Vancomycin Resistant *Enterococcus* (VRE), as well as select Gram-negative pathogens, and targets both typical and atypical pathogens. Remarkably, it is ten times more potent than

azithromycin and achieves equivalent clinical outcomes with a convenient three-day regimen, as validated by clinical trials. As the first new antibiotic in its class to be developed in over three decades, Nafithromycin represents a significant breakthrough in combating antimicrobial resistance.^[3]

Preclinical data suggest nafithromycin is rapidly absorbed with good tissue penetration and a long half-life, suitable for once-daily dosing. Early toxicity studies show mild gastrointestinal side effects, with no major concerns of nephrotoxicity or hepatotoxicity. Further human safety data are needed.^[4]

Nafithromycin, was officially launched on November 20, 2024, by Union Minister Dr. Jitendra Singh. Developed by Wockhardt with support from the Biotechnology Industry Research Assistance Council (BIRAC), Nafithromycin, marketed as "Miqnaf," targets Community-Acquired Bacterial Pneumonia (CABP) caused by drug-resistant bacteria, which disproportionately affects vulnerable populations such as children, the elderly, and those with compromised immune systems.

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Nafthromycin shows strong potential in combating resistant bacterial infections, especially MRSA and VRE. India's proactive efforts to combat antimicrobial resistance (AMR) through innovative drug development, such as the launch of Nafithromycin, alongside comprehensive national initiatives, underscore the country's leadership in global healthcare. The commitment to surveillance, awareness, and international collaboration highlights India's strategic approach in tackling AMR and improving health outcomes.

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