THE SCIENCE WORLD
A Monthly e Magazine
ISSN:2583-2212
Popular article
July, 2026 Vol.6(7), 2189-2192

Zaynich: Made in India, Approved by the FDA

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doi.org/10.5281/ScienceWorld.21828012

Introduction

Antimicrobial resistance (AMR) among Gram-negative bacteria has emerged as a major global health challenge, limiting the effectiveness of existing antibiotics and increasing morbidity, mortality, and healthcare costs. The threat of drug-resistant infections is an escalating crisis, leaving clinicians with fewer tools to treat patients facing these aggressive pathogens. Complicated urinary tract infections (cUTIs), particularly those caused by multidrug-resistant (MDR) pathogens, are increasingly difficult to treat and are associated with prolonged hospitalization and serious complications, highlighting the need for novel therapeutic agents.

Against this backdrop, Zaynich, a novel injectable antibiotic developed by the Mumbai-based pharmaceutical company Wockhardt, received approval from the United States Food and Drug Administration (FDA) on 29 May 2026. This review provides a brief overview of the composition, mechanism of action, clinical efficacy, approved indications, and safety profile of ZAYNICH, highlighting its potential role in addressing the growing challenge of antimicrobial resistance.

Zaynich: A novel intravenous antibiotic

On 29 May 2026, the United States Food and Drug Administration (FDA) approved ZAYNIC (cefepime–zidebactam), a novel intravenous antibiotic developed by Wockhardt, for the treatment of adults with complicated urinary tract infections (cUTIs), including

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Published 30/07/2026

pyelonephritis, caused by susceptible Gram-negative bacteria. ZAYNICH combines cefepime, a fourth-generation cephalosporin, with zidebactam, a first-in-class β-lactam enhancer that restores and enhances the antibacterial activity of cefepime through a unique dual mechanism of action.

The approval of ZAYNICH is a significant milestone, as it is the first new chemical entity (NCE) to be fully discovered, developed, and commercialized by an Indian pharmaceutical company to receive FDA approval.

Composition and Mechanism of Action

ZAYNICH is an injectable antibiotic comprising of cefepime, a fourth-generation cephalosporin antibacterial, and zidebactam, a a non-β-lactam antibacterial and β-lactamase inhibitor that also functions as a beta-lactamase inhibitor. Cefepime primarily targets penicillin-binding protein-3 (PBP3) and PBP1a/b in Enterobacterales, and PBP3 in other Gram-negative pathogens, thereby disrupting bacterial cell-wall synthesis. Zidebactam contributes a distinct and complementary mechanism, selectively inhibits penicillin-binding protein-2 (PBP2).

What differentiates Zaynich from most other beta-lactam/beta-lactamase-inhibitor combinations is that it does not rely on a single point of attack. Instead, zaynich targets multiple penicillin-binding proteins (PBP 1a/b, 2 and 3) simultaneously. This novel, multi-target synergy allows Zaynich to retain bactericidal activity even in the presence of β-lactamases, including metallo-beta-lactamases (MBLs), which are not inhibited by zidebactam. The combination is also designed to overcome non-enzymatic resistance mechanisms such as hyper-efflux and downregulation of outer membrane porin channels..

The ENHANCE-1 Trial

FDA approval of Zaynich was supported in substantial part by data from the Phase 3 ENHANCE-1 clinical trial. In this trial, Zaynich met its primary efficacy endpoint, achieving a composite clinical cure and microbiological response rate of 89.0%, compared with 68.4% for the comparator antibiotic, meropenem widely regarded as a benchmark therapy for serious Gram-negative infections.

Indications and Dosage

Zaynich is indicated for the treatment of adult patients with complicated urinary tract infections (cUTI) including pyelonephritis caused by the following susceptible microorganisms: *Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, Enterobacter cloacae* complex, and *Pseudomonas aeruginosa*. It should be used to reduce development of

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drug resistance bacteria and only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

The recommended dosage for adult patients with an estimated glomerular filtration rate (eGFR) greater than equal to 60 mL/min is 3 grams of Zaynich (comprising 2 grams cefepime and 1 gram zidebactam), administered by intravenous infusion over one hour, every 8 hours, for a treatment duration of 7 to 10 days. Dosage adjustment is required for patients with renal impairment (eGFR below 60 mL/min), with infusion timing similarly maintained at one hour per dose.

Safety Profile

The prescribing information for Zaynich lists several important warnings and precautions, including the risk of serious hypersensitivity reactions, neurotoxicity, and *Clostridioides difficile*-associated diarrhoea, the latter being a recognised class effect of broad-spectrum antibacterial agents.. The most commonly reported adverse reactions,occurring in ≥2% of patients in clinical trials, were diarrhoea, headache, hypertension, and hypokalemia. As with other antibacterial agents, Zaynich is intended solely for confirmed or strongly suspected bacterial infections, and its prescribing information explicitly cautions against inappropriate use in order to limit the further emergence of drug-resistant bacteria.

Broader Significance

Beyond its immediate clinical utility, Zaynich carries symbolic and strategic weight for the Indian pharmaceutical sector. India has long been recognised as a global hub for high-quality, affordable generic medicines, but originating an entirely novel molecule and carrying it through the full discovery-to-approval pipeline is a fundamentally different undertaking, requiring sustained investment in early-stage research, mechanistic innovation, and multi-phase clinical development. Zaynich's approval is therefore being viewed within the industry as evidence that Indian pharmaceutical companies are capable of competing at the frontier of novel antibiotic discovery, at a time when the global pipeline for new antibiotics against Gram-negative pathogens has been widely described as thin. Given that carbapenem-resistant infections currently leave clinicians dependent on older, more toxic last-resort agents such as colistin and polymyxins, an effective and better-tolerated alternative such as Zaynich addresses a genuine and urgent unmet clinical need.

Conclusion

Zaynich (cefepime and zidebactam) represents a scientifically distinctive addition to the antibacterial armamentarium against cUTIs caused by multidrug-resistant Gram-negative

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organisms. Its multi-target mechanism, strong performance against meropenem in the pivotal ENHANCE-1 trial, and status as the first New Chemical Entity fully developed and commercialized by an Indian pharmaceutical company to receive an FDA approval, representing a historic milestone not only for Wockhardt, but for the Indian pharmaceutical industry.

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