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Review Paper

Oral Penems and Antimicrobial Stewardship: Is Faropenem a Friend or Foe? A Comprehensive Review

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ABSTRACT

Faropenem stands out as a unique oral penem antibiotic with activity against both Gram-positive and Gram-negative bacteria, including strains that produce extended-spectrum β-lactamases (ESBLs). Though commonly prescribed across Asian nations—especially Japan and India—its place in contemporary antimicrobial stewardship remains hotly debated. This comprehensive review examines faropenem's pharmacological characteristics, clinical effectiveness, resistance concerns, regulatory status, and appropriate positioning in modern treatment protocols. Available evidence raises significant red flags about carbapenem cross-resistance, gaps in surveillance systems, and limited high-quality research. The World Health Organization's designation of faropenem as a RESERVE antibiotic highlights the critical need for careful prescribing to protect carbapenem effectiveness for life-threatening infections.

Keywords: Faropenem, penem antibiotics, antimicrobial stewardship, carbapenem resistance, ESBL, rational prescribing

INTRODUCTION

The growing crisis of antimicrobial resistance demands careful examination of how we prescribe antibiotics worldwide. Within this challenging landscape, faropenem—a synthetic oral β-lactam from the penem family—occupies a controversial position in clinical practice. While structurally related to carbapenems yet pharmacologically distinct, faropenem shows powerful activity against multidrug-resistant organisms while simultaneously raising concerns about promoting resistance to last-resort carbapenem agents.

Faropenem's unique molecular structure features a distinctive chiral tetrahydrofuran ring at the C2 position, which provides enhanced chemical stability and reduced neurotoxicity compared to earlier carbapenem formulations, such as imipenem. This structural modification enables oral administration, positioning faropenem as one of the few orally available agents with carbapenem-like activity. Since gaining initial approval in Japan in 1997 and subsequent introduction in India in 2005, faropenem has achieved substantial market penetration for treating respiratory, urinary tract, skin & soft tissue, gynecological, and paediatric infections [1].

However, faropenem's expanding use occurs against a backdrop of incomplete understanding regarding its resistance implications, limited high-quality clinical evidence, and absence of standardized susceptibility testing guidelines. The medication remains unapproved by the United States Food and Drug Administration, reflecting regulatory concerns about efficacy demonstration and resistance surveillance. This comprehensive review synthesizes current knowledge on faropenem's clinical role, examines controversies surrounding its classification and use, evaluates its impact on global resistance patterns, and proposes evidence-based prescribing frameworks consistent with antimicrobial stewardship principles.

1. Pharmacological Profile and Antimicrobial Activity

Chemical Structure and Mechanism of Action

Faropenem belongs to the penem class of β-lactam antibiotics, characterized by a β-lactam ring fused to a five-membered structure containing sulfur at position 1 and carbon at position 2. This distinguishes penems from carbapenems, which contain carbon at position 1. Despite this structural difference, faropenem exhibits carbapenem-like antibacterial properties through inhibition of bacterial cell wall synthesis via binding to penicillin-binding proteins.

The incorporation of a tetrahydrofuran ring at the C2 position represents a critical structural innovation, providing several clinical advantages. This modification enhances resistance to dehydropeptidase-I degradation in renal tubules, eliminating the requirement for co-administration of enzyme inhibitors. Additionally, the structural configuration reduces penetration across the blood-brain barrier, thereby minimizing seizure risk—a significant limitation of older carbapenems [1].

Spectrum of Antimicrobial Activity

Faropenem demonstrates broad-spectrum bactericidal activity against clinically significant pathogens. Laboratory studies reveal notable potency against penicillin-susceptible and penicillin-resistant Streptococcus pneumoniae, with effectiveness surpassing amoxicillin-clavulanate combinations. Activity against methicillin-susceptible Staphylococcus aureus is documented, though methicillin-resistant strains demonstrate resistance.

For gram-negative organisms, faropenem displays excellent activity against Enterobacterales, including Escherichia coli, Klebsiella pneumoniae, Proteus mirabilis, and Haemophilus influenzae. Critically, faropenem maintains activity against ESBL-producing strains, with modal minimum inhibitory concentrations of 0.5–1 mg/L for ESBL-producing E. coli and Klebsiella species. More than 95% of ESBL producers demonstrate susceptibility at concentrations ≤2 mg/L. [5]

However, faropenem demonstrates reduced or absent activity against *Pseudomonas aeruginosa*, *Acinetobacter* species, *Stenotrophomonas maltophilia*, and *Enterococcus* species, limiting its utility in healthcare-associated infections where these organisms predominate.

Pharmacokinetics and Pharmacodynamics

Faropenem is available in two formulations with distinct pharmacokinetic profiles: faropenem sodium (active drug) and faropenem medoxomil (ester prodrug requiring conversion to active form). Following oral administration of 300 mg faropenem sodium, peak serum concentrations of 10–14 mg/L are achieved within 1–2 hours. The medication demonstrates approximately 30–40% oral bioavailability, with protein binding of approximately 95%. The elimination half-life ranges from 1.0–1.5 hours, necessitating three-times-daily dosing for optimal therapeutic effect.

Renal excretion represents the primary elimination pathway, with approximately 30–40% of the administered dose recovered unchanged in urine. This results in exceptionally high urinary concentrations: 70 mg/L during 0–4 hours post-administration and 12 mg/L during 4–8 hours post-administration. These concentrations substantially exceed the minimum inhibitory concentration for ESBL-producing E. coli, supporting efficacy in uncomplicated urinary tract infections.

As a β-lactam antibiotic, faropenem exhibits time-dependent bactericidal activity, with efficacy correlated to the duration that serum concentrations remain above the minimum inhibitory concentration. Optimal bactericidal effects typically require maintaining adequate drug levels for 40–50% of the dosing interval.

2. Clinical Efficacy and Therapeutic Applications

Respiratory Tract Infections

Clinical trials conducted primarily in Asian populations have evaluated faropenem's efficacy in community-acquired respiratory infections. Studies examining acute bacterial exacerbations of chronic bronchitis demonstrated clinical success rates of 85–92%, with favorable bacteriological eradication rates against S. pneumoniae and H. influenzae. Pediatric studies evaluating faropenem for acute otitis media and pharyngotonsillitis reported comparable efficacy to standard comparators such as amoxicillin-clavulanate, with clinical cure rates exceeding 90%.

Surveillance data from U.S. clinical isolates demonstrate that faropenem retains substantial in-vitro activity against key respiratory pathogens, including penicillin-resistant *Streptococcus pneumoniae*. Its activity against both β-lactamase–producing and non-producing strains of *Haemophilus influenzae* and *Moraxella catarrhalis* further highlights its broad antimicrobial spectrum. The favourable MIC_{90} distribution across these organisms supports the potential utility of faropenem as an oral therapeutic option for community-acquired respiratory tract infections [4]

However, methodological limitations affect the interpretation of these findings. Many studies lacked placebo controls, employed non-inferiority designs with wide confidence intervals, and enrolled predominantly Asian populations, which may have limited their generalizability. The FDA's rejection of faropenem medoxomil was partly influenced by evolving regulatory standards requiring placebo-controlled superiority trials for respiratory infections, particularly given the high spontaneous resolution rates in conditions such as acute sinusitis.

Urinary Tract Infections

ESBL-producing Enterobacteriaceae, especially CTX-M–type strains, are increasingly responsible for community-onset infections and have limited oral treatment options. Faropenem, an oral penem antibiotic, has emerged as a potential alternative due to its stability and broad activity against ESBL-producing pathogens. Studies show that faropenem retains good in-vitro activity against most ESBL-producing *E. coli* and *Klebsiella* spp., but its effectiveness is reduced against organisms with high-level AmpC expression, such as *Enterobacter*, *Citrobacter*, and *Serratia*. These findings suggest that faropenem may be useful for ESBL-related community infections—particularly urinary tract infections—although further clinical and pharmacokinetic data are needed to define its optimal role.[3]

For complicated urinary tract infections and pyelonephritis caused by ESBL producers, observational studies suggest potential utility as step-down oral therapy following initial intravenous carbapenem treatment. However, prospective randomized controlled trials comparing faropenem to established alternatives such as fluoroquinolones or trimethoprim-sulfamethoxazole remain absent from the literature.

Skin and Soft Tissue Infections

Limited data support faropenem's use in uncomplicated skin and soft tissue infections caused by gram-positive cocci and susceptible gram-negative organisms. Small studies reported clinical success rates of 80–88% for cellulitis, wound infections, and abscesses [1]. However, the prevalence of methicillin-resistant *S. aureus* in many geographic regions and faropenem's lack of activity against this pathogen limit its empirical utility without microbiological confirmation.

Pediatric Applications

Faropenem oral suspension has been extensively studied in pediatric populations in India and Japan. Indications include acute otitis media, pharyngotonsillitis, pneumonia, and urinary tract infections. Pediatric studies generally report favorable safety profiles with clinical efficacy comparable to comparator agents. The drug generally demonstrates good tolerability across age groups, with the most commonly reported adverse effects including gastrointestinal disturbances (5–15%), particularly diarrhea, nausea, and abdominal discomfort.

Emerging Applications in Tuberculosis

Preliminary research has explored faropenem's potential role in drug-resistant tuberculosis treatment regimens. Preclinical investigations demonstrated that faropenem exhibits superior bactericidal activity against *Mycobacterium tuberculosis* compared to meropenem, with 6- to 22-fold faster inactivation of l,d-transpeptidases—enzymes critical for mycobacterial cell wall synthesis. While clinical trials have been conducted, published results remain limited, and this represents an intriguing potential application requiring substantial additional investigation.

3. Resistance Concerns and Cross-Resistance Mechanisms

The Cross-Resistance Dilemma

The most significant concern regarding faropenem use centers on potential promotion of carbapenem resistance through cross-resistance mechanisms. Multiple lines of evidence support this concern and deserve serious attention from prescribers and policymakers. Laboratory experiments exposing ESBL-producing Enterobacterales to faropenem have demonstrated induction of multiple resistance mechanisms, including β-lactamase overproduction, porin mutations (particularly loss of OmpK35/36 in Klebsiella species), and upregulation of efflux pump systems. These adaptations can confer reduced susceptibility to carbapenems, even in the absence of carbapenemase production.

The structural similarity between faropenem and carbapenems means both drug classes serve as substrates for overlapping resistance determinants. Selection pressure from faropenem use may promote expansion of bacterial populations harboring mutations that compromise carbapenem efficacy [7]. Furthermore, studies have shown that faropenem reacts with both serine and metallo-β-lactamases to give multiple products, which may contribute to the evolution of cross-resistant bacterial strains.

Faropenem demonstrates clinically relevant in-vitro activity against ESBL-producing *Escherichia coli* and *Klebsiella* species, including CTX-M enzymes that now predominate in community-onset infections. The consistently low MIC values observed for these pathogens support the potential role of faropenem as an oral treatment option, particularly where resistance to third-generation cephalosporins limits standard therapies.

In contrast, activity was diminished against *Enterobacter*, *Citrobacter*, and *Serratia* species with derepressed AmpC expression, with a subset of isolates requiring markedly higher MICs. These findings indicate that faropenem may be unreliable for infections caused by AmpC-producing organisms, especially in severe disease or when high bacterial burden is anticipated. Only selected carbapenemases, notably NMC-A and IMP types, produced substantial increases in MICs, suggesting relative stability of faropenem against many β-lactamase mechanisms.[10]

From an antimicrobial stewardship perspective, faropenem may represent a carbapenem-sparing oral option for targeted treatment of community-acquired urinary tract infections due to ESBL-producing *E. coli* and *Klebsiella* species. However, its use should be guided by susceptibility testing, with avoidance in suspected or confirmed AmpC-derepressed infections. Stewardship programmes should also consider pharmacokinetic exposure at the urinary site when defining its role in step-down or outpatient therapy [6,7]

Epidemiological Evidence and Regional Patterns

Countries reporting increased faropenem utilization, particularly India, have simultaneously observed rising prevalence of multidrug-resistant Enterobacterales in community settings. While establishing direct causation remains difficult due to multiple confounding factors, the temporal association warrants serious consideration. Available data from regions with established faropenem use suggest concerning trends. Studies from India have documented the proportion of E. coli urinary isolates producing ESBLs rising from approximately 40% in 2010 to over 70% in some urban centers by 2020.

Carbapenem-resistant *Enterobacterales* rates in Indian hospitals have increased substantially, with some institutions reporting prevalence exceeding 15% for *K. pneumoniae* isolates. Most worryingly, concerning reports describe detection of carbapenem-resistant organisms in community-acquired infections, suggesting resistance dissemination beyond healthcare facilities.

Surveillance Infrastructure Gaps

A critical impediment to understanding faropenem's resistance impact is the absence of standardized susceptibility testing guidelines. Neither the Clinical and Laboratory Standards Institute nor the European Committee on Antimicrobial Susceptibility Testing has established interpretative breakpoints for faropenem. Consequently, routine susceptibility testing is not performed in most clinical microbiology laboratories, creating substantial surveillance blind spots.

This absence of systematic monitoring prevents accurate assessment of temporal trends in faropenem susceptibility, geographic variation in resistance prevalence, correlation between faropenem use intensity and resistance rates, and cross-resistance patterns with carbapenems and other β-lactams. Without this fundamental data, we're essentially operating without adequate visibility regarding faropenem's true resistance impact.

4. Regulatory Landscape and Global Stewardship Guidelines

Global Regulatory Status

Faropenem has achieved regulatory approval in only a limited number of Asian countries. Japan approved faropenem in 1997 through its Pharmaceuticals and Medical Devices Agency, where it has been marketed for over two decades. However, utilization remains relatively constrained compared to other oral antibiotics, with professional guidelines recommending judicious use. India's Central Drugs Standard Control Organisation approved faropenem sodium tablets in 2005, with subsequent approval of oral suspension in 2021. India represents the largest market for faropenem globally, with widespread availability and marketing.[8]

The FDA Rejection and European Absence

Faropenem medoxomil underwent extensive clinical development for the U.S. market during the early 2000s. The FDA issued a non-approvable letter in 2006, citing multiple deficiencies. Clinical trial data were deemed insufficient to establish superiority over placebo for acute bacterial sinusitis and acute exacerbations of chronic bronchitis—conditions with high spontaneous resolution rates. Although not the primary basis for rejection, regulatory reviewers expressed concerns about potential resistance implications in the absence of robust surveillance mechanisms.

The developer subsequently discontinued pursuit of U.S. approval, and as of 2025, faropenem medoxomil remains unavailable in the United States. Faropenem has not been submitted for evaluation by the European Medicines Agency, and neither formulation is approved in European Union member states.[12]

WHO RESERVE Classification

The World Health Organization's 2021 AWaRe (Access, Watch, Reserve) classification system designates faropenem as a RESERVE antibiotic. This categorization indicates that faropenem should be reserved as a last-resort option for treatment of confirmed or suspected infections due to multidrug-resistant organisms when all alternatives have been exhausted or are unsuitable. The RESERVE classification reflects WHO's assessment that faropenem's carbapenem-like properties warrant strict stewardship controls to preserve efficacy of this antibiotic class. This represents the most conservative categorization in the WHO system, placing faropenem alongside carbapenems, tigecycline, and colistin.[11]

Expert Guidelines and Recommendations

The Indian Council of Medical Research Treatment Guidelines for Antimicrobial Use in Common Syndromes (2019) provide specific recommendations regarding faropenem. The guidelines explicitly state faropenem is not recommended for empirical treatment of community-acquired infections and should not be used as step-down therapy following intravenous carbapenems unless compelling patient-specific factors exist. It should be reserved for documented ESBL infections when established alternatives are unsuitable and requires antimicrobial stewardship approval in hospital settings.

Japanese guidelines from the Society for Infection and Chemotherapy emphasize judicious faropenem use despite its long availability. They recommend restricting faropenem to second-line status, encourage susceptibility testing before use, discourage empirical use for uncomplicated infections, and promote use of narrow-spectrum agents whenever feasible.

5. Rational Prescribing Framework and Future Research Directions

Appropriate Clinical Scenarios

Based on current evidence and stewardship principles, faropenem use should be restricted to specific clinical circumstances. The drug may be appropriate for documented ESBL-producing *Enterobacterales* infections, particularly uncomplicated cystitis or pyelonephritis with confirmed ESBL-producing *E. coli* or *Klebsiella* species, when contraindications or intolerance exist to fluoroquinolones and trimethoprim-sulfamethoxazole, with susceptibility to faropenem confirmed by laboratory testing where available, and preference for oral therapy based on patient-specific factors.[3]

For step-down therapy considerations, faropenem should only be considered after clinical improvement with parenteral therapy, when oral agents with established efficacy are unavailable or contraindicated, with documented microbiological cure and appropriate pharmacokinetic considerations, and under close clinical monitoring with clearly defined failure criteria.

Inappropriate Uses

Faropenem should be avoided for empirical therapy in the absence of microbiological documentation, as alternative agents with established efficacy profiles should be preferred. It should not be used for mild infections responsive to narrow-spectrum agents—conditions such as uncomplicated cystitis caused by susceptible organisms should be treated with first-line agents like nitrofurantoin, trimethoprim-sulfamethoxazole, or fosfomycin. Faropenem's limited activity against *Pseudomonas aeruginosa* precludes use in infections where this organism is suspected. Prophylactic administration for surgical procedures or recurrent infections lacks evidence support and violates stewardship principles [9]

Dosing Recommendations and Clinical Monitoring

Standard dosing regimens for faropenem sodium in adults include 200 mg three times daily for uncomplicated infections and 300 mg three times daily for complicated infections, with duration of 5–7 days for uncomplicated urinary tract infections and 10–14 days for complicated infections. Pediatric patients receive weight-based dosing of 8–12 mg/kg three times daily, with a maximum daily dose of 900 mg.

Dose adjustments are necessary for renal impairment: with creatinine clearance 30–50 mL/min, standard dose twice daily; with creatinine clearance <30 mL/min, 200 mg twice daily; for hemodialysis patients, 200 mg after each dialysis session. Patients receiving faropenem should undergo clinical monitoring including symptom resolution assessment at 48–72 hours, temperature normalization in febrile patients, and adverse event surveillance. Microbiological monitoring should include repeat cultures 5–7 days post-treatment for complicated infections, susceptibility testing if isolates are recovered, and surveillance for resistance emergence.

Research Priorities

The global rise in antibiotic resistance represents a major threat to public health, prompting the WHO to expand its focus beyond multidrug-resistant tuberculosis. Using a structured multicriteria decision analysis, antibiotic-resistant bacteria were prioritised based on clinical impact, resistance trends, and treatment limitations. Gram-negative pathogens, particularly carbapenem-resistant *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and resistant Enterobacteriaceae, were classified as critical priorities. High-priority pathogens also included vancomycin-resistant *Enterococcus faecium* and meticillin-resistant *Staphylococcus aureus*. These findings highlight the urgent need for antibiotic development targeting multidrug-resistant Gram-negative organisms, including those causing community-acquired infections.[6] The medical community urgently needs placebo-controlled efficacy trials in well-defined populations, comparative effectiveness studies versus established alternatives, and prospective studies systematically evaluating resistance emergence. Establishment of standardized susceptibility testing with interpretative breakpoints represents a fundamental prerequisite for rational use. Specific research needs include rigorous trials assessing faropenem's efficacy against placebo and active comparators in well-defined infection syndromes, head-to-head trials comparing faropenem with fluoroquinolones and other alternatives for ESBL infections, and prospective studies evaluating systematic step-down protocols from intravenous carbapenems to oral faropenem.

Long-term surveillance networks tracking faropenem susceptibility trends, cross-resistance patterns, and correlation with carbapenem use are essential. Whole-genome sequencing studies characterizing resistance mechanisms emerging during faropenem exposure and assessing clonal dissemination patterns would provide valuable insights.

CONCLUSION

Faropenem occupies a controversial position in antimicrobial therapy, offering theoretical benefits as an oral agent against ESBL-producing organisms while simultaneously raising serious concerns about promoting carbapenem resistance. The current evidence base is inadequate, with most studies geographically limited and lacking rigorous comparisons, while laboratory data consistently shows faropenem exposure can select for resistance mechanisms that compromise carbapenem effectiveness. The absence of standardized susceptibility testing creates major surveillance gaps preventing accurate resistance assessment.

Under current evidence, faropenem's appropriate clinical role is extremely narrow—acceptable only for documented ESBL-producing Enterobacterales infections, particularly uncomplicated urinary tract infections, when standard alternatives are contraindicated or unavailable. It is unacceptable for empirical therapy, mild infections, routine step-down following IV carbapenems, or prophylaxis. Major health organizations including WHO, the Indian Council of Medical Research, and Japanese medical societies recommend strict restrictions, contradicting marketing claims that position faropenem as a broadly applicable "oral carbapenem."

Faropenem should be viewed as a high-risk, last-resort carbapenem-sparing option rather than a convenient first-line alternative. Healthcare systems permitting its use must implement mandatory stewardship controls including infectious diseases consultation, microbiological documentation, documented rationale for alternative agent unsuitability, and systematic resistance monitoring. Without such safeguards, widespread unrestricted use risks contributing to the escalating global carbapenem resistance crisis, with devastating public health implications. Preserving carbapenem efficacy for life-threatening infections must take precedence over convenience and cost considerations.

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