

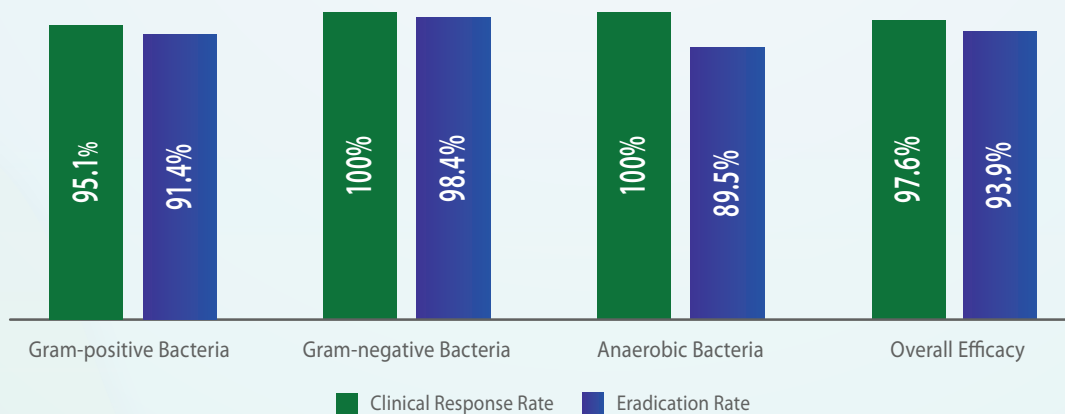
CLINICAL STUDIES OF FAROPENEM IN THE FIELD OF OBSTETRICS AND GYNECOLOGY

A multicenter, prospective clinical study was conducted across 10 medical institutions in Yamagata Prefecture, Japan from April 1998-March 1999, to evaluate the clinical efficacy, bacteriological response, and safety of Faropenem in the treatment of mild-to-moderate outpatient infections in the field of obstetrics and gynecology.

Methodology	Clinical Efficacy of Faropenem in Obstetric & Gynecological Infections ¹		
	Conditions	Number of Cases	Efficacy Rate
<p>165 Patients with mild to moderate gynecological and related infections</p> <p>Study Period 1 Year</p> <p>Dosing Regimen Faropenem 200 mg orally, three times daily for 3 to 7 days</p> <p>Symptoms Assesment at Day 3 & 7</p>	Endometritis	47	97.9 %
	Adnexitis	25	92.0 %
	External genital infections (Vulvitis, Bartholin's adenitis, Vulval abscess)	16	93.8 %
	Mastitis	9	88.9 %
	Cystitis	67	94.0 %
	Cervicitis	1	100 %

- ▶ The overall clinical efficacy of faropenem was 94.5% (156/165 cases), indicating a high therapeutic success rate across a spectrum of gynecological infections.
- ▶ No side effects or abnormal lab findings were observed in any case.

Bacteriological Efficacy of Faropenem in Obstetric & Gynecological Infections¹



- ▶ A total of 165 bacterial strains were isolated from 106 patients, with results indicating robust bactericidal activity across various organisms.

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Faropenem 150 mg & 200 mg Tablet



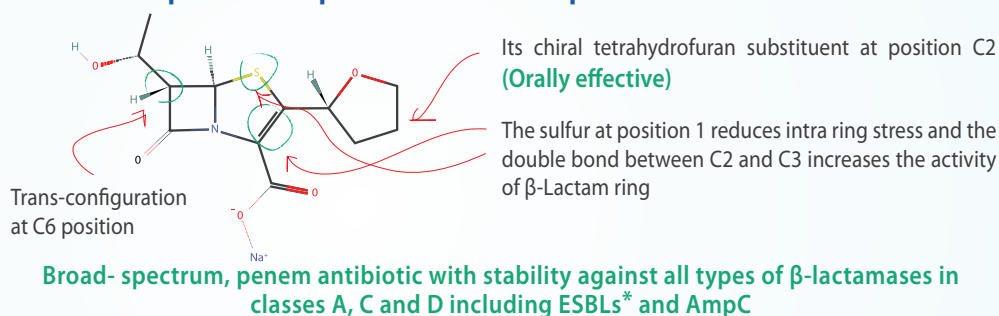
Drug Review

Antimicrobial resistance

- Antimicrobial resistance (AMR) has been prioritized by the World Health Organization (WHO) as one of the top 10 global public health threats facing humanity.²
- Resistance to beta-lactams is an alarming and growing phenomenon and, in turn, a public health challenge. Following are the mechanisms of resistance³ :
 - Inactivation by the production of beta-lactamases.
 - Decreased penetration to the target site (e.g., the resistance of *Pseudomonas aeruginosa*).
 - Alteration of target site Penicillin Binding Proteins (PBPs) (e.g., penicillin resistance in *pneumococci*).
 - Efflux from the periplasmic space through specific pumping mechanisms.

The key distinguishing features of faropenem⁴⁻⁷

Faropenem- a penem with unique chemical structure



Time, concentration and oxygen dependent **bactericidal effect** against **Aerobic, Anaerobic, Gram-positive & Gram-negative** bacteria.

Faropenem has shown lower MICs (Minimum Inhibitory Concentrations) than other beta-lactam antibiotics against certain bacteria.

Bacteria	Faropenem			Amox - clav		Cefuroxime		Imipenem	
	MIC ₅₀	MIC ₉₀	Range	MIC ₅₀	MIC ₉₀	MIC ₅₀	MIC ₉₀	MIC ₅₀	MIC ₉₀
<i>Staphylococcus aureus</i> (MS)	0.12	0.12	0.03–0.5	1	2	1	2	≤ 0.5	≤ 0.5
<i>S. aureus</i> (MR)	>32	>32	0.12–>32	8	16	>32	>32	32	32
<i>Staphylococcus epidermidis</i> (All)	0.12	0.5	0.06 – >128	1	8	0.5	16	0.016	16
<i>S. epidermidis</i> (MS)	0.12	0.5	0.06 – 4	1	2	0.5	1	0.016	0.016
<i>Streptococcus pyogenes</i>	0.03	0.03	≤ 0.015 – 0.06	0.03	0.03	≤ 0.015	≤ 0.015	≤ 0.008	≤ 0.008
<i>Streptococcus pneumoniae</i>	0.008	0.25	≤ 0.004 – 2	0.03	0.5	≤ 0.12	4	≤ 0.5	≤ 0.5
<i>Escherichia coli</i>	0.5	1	0.12 – 32	4	16	4	8	≤ 0.5	≤ 0.5
<i>Haemophilus influenzae</i>	0.25	1	≤ 0.004 – 4	0.5	1	0.5	2	1	4
<i>H. influenzae</i> (BLN)	0.25	1	≤ 0.004 – 4	0.5	1	0.5	2	1	2
<i>Klebsiella pneumoniae</i>	0.5	2	0.25 – >32	2	8	4	>32	0.25	1

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