

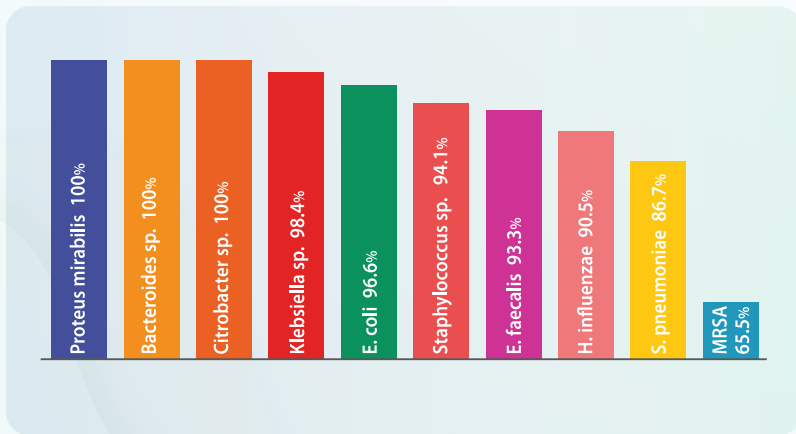
# Efficacy & safety of Faropenem in post marketing surveillance study

Faropenem is a broad-spectrum oral penem antibiotic approved in Japan in 1997. Known for its stability against  $\beta$ -lactamases and efficacy against Gram-positive, Gram-negative, and anaerobic bacteria, it was introduced as a new option for community-acquired infections. A nationwide post-marketing use-results surveillance study was conducted in Japan to evaluate its real-world effectiveness and safety.

Study design	Observational, multicenter post-marketing surveillance study		
<b>Patients</b>  <b>19,375</b>	<b>Duration</b>  <b>4 years</b>	<b>Centers</b>  <b>2,826</b> Medical institutions across Japan	<b>Intervention</b>  Faropenem <b>150–300 mg</b> TID depending on severity and infection type

**Efficacy** Clinical effectiveness exceeding **85%** in all approved indications, reinforcing the reliability of Faropenem's pre-marketing evaluations.

**Safety** Only 2.96% adverse events observed than in pre-marketing studies (5.75%).



Therapeutic area	Disease	Efficacy (%) of Faropenem
<b>Surgical</b>	Mastitis, periproctal abscess, secondary infection of burns, external wounds & incisions	<b>98.4 %</b>
<b>Respiratory</b>	Pharyngolaryngitis, acute bronchitis, tonsillitis & pneumonia	<b>95.07 %</b>
<b>Urinary tract</b>	Pyelonephritis, cystitis, prostatitis & epididymitis	<b>94.35 %</b>
<b>Gynecological</b>	Adnexitis, intrauterine infection & bartholinitis	<b>96.72 %</b>
<b>Otorhinolaryngeal</b>	Otitis externa, otitis media & sinusitis	<b>91.11%</b>
<b>Superficial suppurative</b>	Boils, abscess, furunculosis & carbuncles	<b>95.81 %</b>

Clinical efficacy (%) of faropenem in different causative organisms and therapeutic areas

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Faropenem 150 mg & 200 mg Tablet

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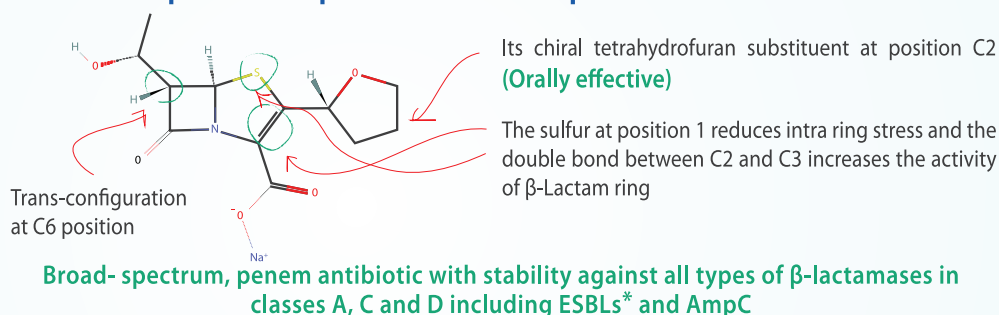
# Drug Review

## 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.<sup>2</sup>
- Resistance to beta-lactams is an alarming and growing phenomenon and, in turn, a public health challenge. Following are the mechanisms of resistance<sup>3</sup> :
  - 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 faropenem<sup>4-7</sup>

### 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 <sub>50</sub>	MIC <sub>90</sub>	Range	MIC <sub>50</sub>	MIC <sub>90</sub>	MIC <sub>50</sub>	MIC <sub>90</sub>	MIC <sub>50</sub>	MIC <sub>90</sub>
Gram (+)ve	<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
Gram (-)ve	<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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