

Lapenem-300

Biapenem for Injection 300 mg

<u>La Renon</u>

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BIAPENEM: Novel Parenteral Carbapenem Antibiotic

- > Biapenem is a broad spectrum carbapenem active against aerobic and anaerobic bacteria including species producing Beta-lactamases.
- > Biapenem shows good bactericidal activity against Gram-positive bacteria including streptococcus pneumoniae, pyogenes and methicillin-susceptible staphylococcus aureus (MSSA). It also shows antibacterial activities against Gram-negative bacteria including resistant Pseudomonas aeruginosa and Acinetobacter baumannii.
- > Evidence from international studies confirmed that biapenem can be used as effectively and safely as meropenem or imipenem/cilastatin in the treatment of various infectious diseases.
- ➤ It is widely distributed and penetrates well into various tissues and body fluids. It can be used twice daily due to its long post-antibiotic effect.¹

BIAPENEM: Unique chemical structure

- > The Early Carbapenems like imipenem are not stable to hydrolysis by human renal dihydropeptidase-I (DHP-I). Therefore, are co-administered with a DHP-I inhibitor e.g. cilastatin.
- Meropenem, Biapenem and Ertapenem are more stable and do not require protection from DHP-I. Comparative in vitro study demonstrate that Biapenem was more stable to hydrolysis by human renal DHP-I than Imipene, Meropenem and Panipenem.

Features of Biapenem

> A Greater bactericidal effect than other carbapenems against P. aeruginosa

- Of 5 tested agents (biapenem, imipenem, meropenem, panipenem and ceftazidime), only biapenem showed bactericidal activity against P. aeruginosa KG5007 (a mutant strain overexpressing MexCD-OprJ).
- Strains of P. aeruginosa resistant to ceftazidime or ofloxacin were also susceptible to Biapenem, as were strains producing β-lactamases.

Improved Tissue Penetration

Widely distributed, penetrates well and achieves clinically relevant concentration into respiratory tract, genitourinary tract, gastrointestinal system & skin

No risk of convulsions/seizures

The presence of a methyl group at the 1ß position, a triazolium radical on the side chain at position 2 and lower potential for biapenem to inhibit GABA receptor binding than imipenem.

Post-antibiotic Effects

Biapenem has shown a marked post antibiotic effect against gram-negative and gram-positive bacteria.²



Clinical Evidence

Biapenem versus meropenem in the treatment of bacterial infections: a multicenter, randomized, controlled clinical trial

Biapenem (1 β -methyl-carbapenem) is stable to most β -lactamases, including AmpC and extended-spectrum β -lactamases (ESBLs), with a broad spectrum activity against Gram-positive and Gram-negative aerobic and anaerobic bacteria.

- * Subjects: 272 Patients diagnosed with bacterial lower respiratory tract infections or UTIs were randomly assigned
- ❖ Dosage: Received either biapenem (300 mg every 12 h) or meropenem (500 mg every 8 h) by intravenous infusion for 7 to 14 days according to their disease severity
- Outcome: Overall clinical efficacy, bacterial eradication rates and drug-related adverse reactions

Table 1: Comparison of clinical efficacy of biapenem and meropenem

Clinical efficacy rate	Biapenem (n=132)	Meropenem (n=132)	
Respiratory tract infection	92.65%	92.54%	
Urinary tract infection	96.88%	95.38%	

Table 2: Bacterial eradication of biapenem and meropenem

Bacteria -	Biapenem (n=132)		Meropenem (n=132)	
	No.	Complete Eradication	No.	Complete Eradication
Gram-Negative	73	69	74	69
Gram-Positive	10	9	6	6

Drug Safety

The rate of drug-related adverse reactions did not differ significantly in biapenem and meropenem groups with the incidence of 11.76 percent (16/136) and 15.44 percent (21/136), respectively.

The overall clinical efficacy and the overall bacterial eradication rates of biapenem and meropenem were equivalent. The rate of drug related adverse reactions did not differ significantly in biapenem and meropenem groups.

Conclusion

Study suggested that biapenem was non-inferior to meropenem and was well-tolerated. Biapenem could be an alternative choice for therapy of moderate and severe lower respiratory tract infections and UTIs.³

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Description

Lapenem-300 (Biapenem for injection) is a novel parenteral broad spectrum Carbapenem class of antibiotic.

Indications

Lapenem-300 is indicated in the following infections:

- Lower respiratory infections- Pneumonia, pulmonary abscess, secondary infection of chronic respiratory lesions,
- Complicated urinary tract infections- cystitis, pyelonephritis,
- Intra-abdominal infections- peritonitis, uterine inflammation/infection & Sepsis.

Mechanism of action

Biapenem penetrates the cell wall of most gram-positive/gram-negative bacteria to bind penicillin-binding protein (PBP) targets and inhibits bacterial cell wall synthesis.

Dosage and Administration

- Biapenem 300 mg twice daily, administered as an infusion over 30 to 60 minutes (600 mg/day).
- Biapenem is available as single 300mg vials and must be reconstituted in 100ml of 0.9% sodium chloride before administration. Dosage can be adjusted according to the age and symptom of individual patient, but should not exceed 1.2 g/day.
- Use for the minimum period necessary to prevent the development of resistant bacteria.
- Patients with severe renal impairment- Monitor and administer Biapenem carefully, reducing the dose or increasing the dosing interval.
- Hemodialysis patients should be administered once daily.

Presentation

Lapenem-300 Injection is supplied as single dose vial.

1. Bei Jia et. al. Chemotherapy 2010;56:285-290

2. Journal of The Association of Physicians of India, Vol. 70, January 2022 3. Indian J Med Res 138, December 2013, pp 995-1002

La Renon Healthcare Private Limited

E-mail: info@larenon.com | Web: www.larenon.com

207-208 Iscon Elegance, Circle P, Prahlad Nagar Cross Roads, S.G. Highway, Ahmedabad-380015, Gujarat, India. Phone: + 91-79-6616-8998, 2693-6656 | Fax: +91-79-6616-8998 Call me on: ©2022 All rights reserved, La Renon Healthcare Private Limited

