

Remedica Co-Amoxiclav



Broad Spectrum Antibiotic with a Wide Coverage of Gram Positive and Gram Negative Bacteria

- Registered in Malaysia since 2009
- Widely Used in Private Clinics,
Government and Private Hospitals in Malaysia



Co-Amoxiclav 375mg

(Amoxicillin 250mg, Clavulanic Acid 125mg per tablet)

Co-Amoxiclav 625mg

(Amoxicillin 500mg, Clavulanic Acid 125mg per tablet)



broad spectrum antibiotic

MY 002-2023
For Healthcare Professional Use Only

Remedica Co-Amoxiclav

A Broad Spectrum Antibiotic with a Wide Coverage of Gram Positive and Gram Negative Bacteria



Bioequivalent Study

Title of Study

A Randomized, Open Label, Two-Sequence, Two-Treatment, Two-Period, Crossover, Single Dose, Bioequivalence Study of Co-Amoxiclav (Amoxicillin/Clavulanate potassium, 500/125 mg) Tablets of Remedica Ltd., with Augmentin 625mg Tablets of GlaxoSmithKline, in Normal, Healthy, Adult, Male Human Subjects under Fasting Condition.

Conclusion:

Co-Amoxiclav 625mg (Amoxicillin 500 mg and Clavulanic Acid 125 mg) Tablet of Remedica Ltd, Cyprus, Europe is bioequivalent to Augmentin amoxicillin + Clavulanate potassium 625 mg (Amoxicillin 500 mg and Clavulanic Acid 125 mg) Tablet of SmithKline Beecham, U.K. in terms of rate and extent of absorption under fasting condition.

Bioequivalence Results:

Pharmacokinetics and Statistical Analysis were performed on data from 46 subjects for Co-Amoxiclav 625mg. The 90% confidence intervals of log-transformed pharmacokinetics parameters for Co-Amoxiclav 625mg are summarised as follows.

Table of Geometric Means and 90% Confidence Interval (N=46)

For Amoxicillin:

Parameters	*Geometric mean		% Ratio	90% Confidence Interval for Log-transformed data	
	Test (A)	Reference (B)		Lower Limit	Upper Limit
AUC _{0-inf}	25099.78	25254.85	99.38	93.80	105.29
AUC _{0-t}	24626.40	24734.02	99.56	93.86	105.61
C _{max}	7130.54	7731.89	92.22	86.65	98.15

For Clavulanic acid:

Parameters	*Geometric mean		% Ratio	90% Confidence Interval for Log-transformed data	
	Test (A)	Reference (B)		Lower Limit	Upper Limit
AUC _{0-inf}	7374.53	6666.63	110.61	100.41	121.86
AUC _{0-t}	7132.48	6422.14	111.06	100.36	122.89
C _{max}	3026.15	2745.24	110.23	98.64	123.18

Geometric mean was taken as the antilog (exponential) of the Least square mean of the log-transformed data.

Prescribing Information

Content: Per 375 tab Amoxicillin 250 mg Clavulanic Acid 125mg Per 625 tab Amoxicillin 500 mg, Clavulanic Acid 125mg. **Indication:** For short-term treatment of bacterial infections of upper resp tract (including ENT) e.g. sinusitis, otitis media, tonsillitis; lower resp tract e.g. acute exacerbation of chronic bronchitis, lobar, bronchopneumonia; genito-urinary tract e.g. cystitis, urethritis, pyelonephritis; Skin & soft tissue e.g. cellulitis, abscesses, boils, wound infections; bone and joint e.g. osteomyelitis; dental infections e.g. dentoalveolar abscess; other infections e.g. septic abortions, puerperal sepsis, intra-abdominal sepsis. **Dosage:** See package insert. **Contra-indications:** Hypersensitivity to active substances, to any of the excipients or to any of the penicillin. History of severe immediate hypersensitivity reaction to other beta-lactam agent (cephalosporin, carbapenem or monobactam). History of jaundice/hepatic impairment due to Clavomid. **Adverse reactions:** GI disturbances (diarrhoea, nausea, vomiting), mucocutaneous candidosis, dizziness, headache, urticarial skin rashes, anaphylaxis. **Presentation & Packaging:** FC tab 375mg x 2 x 10's 625 mg x 2 x 10's.

Dose recommended:

Drug	Mild to Moderate Infection	Severe Infection
Co-Amoxiclav 375 mg	1 Tab TDS 5 - 7 days	-
Co-Amoxiclav 625 mg	1 Tab BD 5 - 7 days	1 Tab TDS 5 - 7 days

Adult & Children >12 years old.

Treatment should not be extended beyond 14 days without review.

* Dosage depends on the age and renal function of the patient and the severity of the infection.

Please refer to package insert for more information.

Remedica
FOR A HEALTHIER WORLD



EUCOGEN

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