

# Single dose, open-label, randomized, two-period, two-treatment, two-sequence crossover bioequivalence study of two montelukast tablets in healthy male volunteers under fasted condition

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## ABSTRACT

**Introduction:** Montelukast (Oxair and Singulair) 5mg, is a selective and orally active leukotriene receptor antagonist which is used for the prophylaxis and treatment of asthma. This study aims to establish bioequivalence and assess the safety and tolerability of two chewable tablets of Montelukast in healthy adults under fasted conditions. **Methods:** An open-label, single-dose, randomized, two-period, two-treatment, two-sequence, crossover study was conducted in healthy adult male subjects with a 7-day washout period. Subjects fasted for a minimum of 8 hours before administration of the tablets. Pharmacokinetic analysis was performed by collecting 5 ml blood samples at various time intervals up to 24.0 hours after drug dosing. Blood samples were centrifuged, and the separated plasma was kept in the freezer at  $-20 \pm 10^{\circ}\text{C}$ . The concentration of montelukast was quantified using a validated liquid chromatography-tandem mass spectrometry method. **Results:** A total of 26 healthy subjects were enrolled, and 25 subjects completed the trial. Statistical analysis revealed no significant differences between  $\text{AUC}_{0-\infty}$ ,  $\text{AUC}_{0-t}$  and  $\text{C}_{\text{max}}$  of two Montelukast tablets for the sequence, period and treatment effects. The 90 % confidence interval for the ratios of  $\text{AUC}_{0-\infty}$ ,  $\text{AUC}_{0-t}$  and  $\text{C}_{\text{max}}$  for the test and reference products were 0.9556-1.0510, 0.9570-1.0539 and 0.9146-1.0660 respectively, which were all within the bioequivalence limit of 0.8000-1.2500 according to the ASEAN guideline acceptance criteria for bioequivalence. Mild adverse events including diarrhoea, headache and upper respiratory tract infections were recorded. **Conclusion:** The test and reference products of Montelukast demonstrated bioequivalence and can be used interchangeably.