

BRONCAST[®]

Montelukast 10 mg

ADD-ON THERAPY FOR BETTER
ASTHMA CONTROL



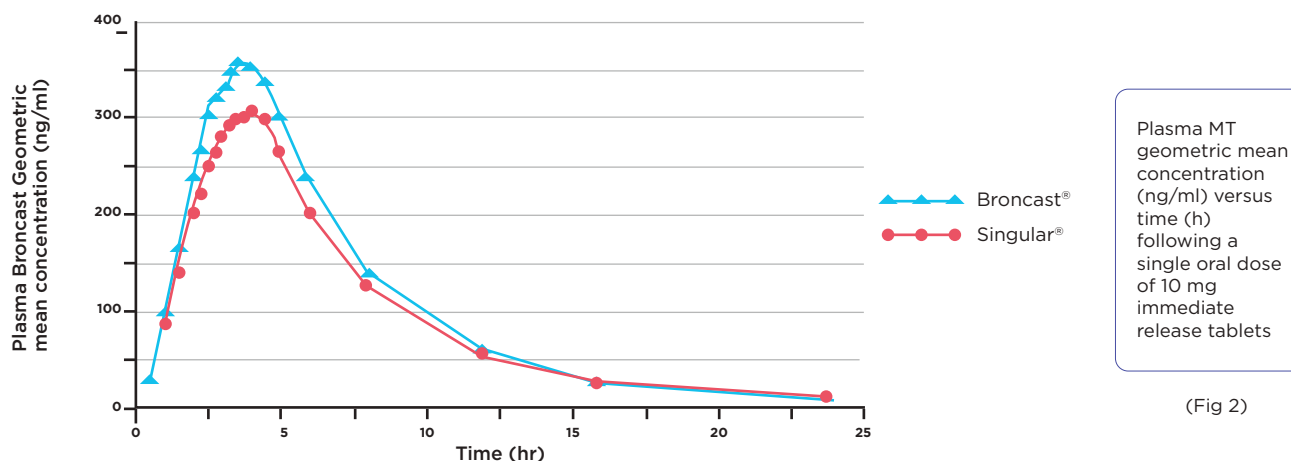
 **Avalon Pharma**

BRONCAST®

Montelukast 10 mg

Add-on therapy
for better
asthma control

- **BRONCAST® 10mg FCT is Bioequivalent to brand Montelukast 10mg FCT with a comparable safety & efficacy profile¹.**

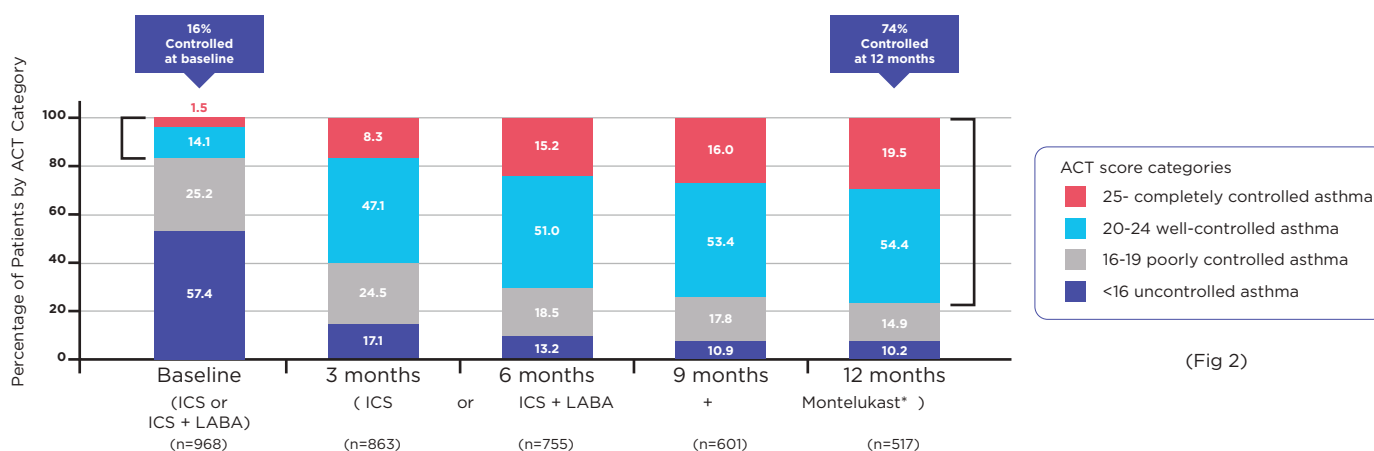


An open-label, randomized two-period crossover bioequivalence design was conducted in 31 healthy male volunteers with 1 week washout between each study period and under fasting conditions. The plasma drug concentration was assessed by using a previously validated LC MS/MS method. The ratio between the generic and brand of geometric least squares means was reported for both Broncast & Brand Montelukast.

Results: Statistical comparison of the main pharmacokinetic parameters showed the inexistence of any significant difference between generic and the brand. The 90% confidence (CIs) were within the pre-defined limits of 80.00-125.00% as specified by the FDA and EMA for bioequivalence studies

- **Adding BRONCAST "Montelukast" to "ICS+LABA" or "ICS" will result in better asthma control⁽²⁾**

At 12 months, 3 of 4 patients achieved asthma control



A 6 months prospective, open-label, observational study with a 6-months extension of 1,681 patients ≥ 18 years with mild to moderate asthma insufficiently controlled by ICS or ICS+LABA treatment. At visit 1 (baseline), asthma control was assessed with 5-question asthma control test (ACT), the primary end point and asthma related quality of life was assessed using the (mini-AQLA) (Juniper). Spirometry was measured if considered necessary by the physician.

Patients received montelukast 10 mg for self administration at visit 1 in addition to their current asthma treatment (SABA, ICS, LABA, fixed combination of ICS+LABA, theophylline, or oral corticosteroids). Additional visits were scheduled after 3, 6, 9 and 12 months. Efficacy analysis was performed for the intention-to-treat and pre-protocol populations, where as safety was evaluated using the total set of patients.

Controlled patients consisted of 54.4% with well controlled asthma and 19.5% with completely controlled asthma.

ACT is a validated, patient-based, 5 item questionnaire designed to identify degree of asthma control in which each item is scored using a scale of 1 to 5, 1 being worst and 5 best.

Dosage & Administration:

BRONCAST "10 mg": (15 years onwards) one 10 mg tablet daily to be taken in the evening

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1. Zaid AN, Mousa A, Ghazal N, Bustamir. Interchangeability and comparative effectiveness between generic and brand montelukast immediate release tablets after a single oral administration in healthy volunteers. Clin Trans Allergy, 2015; 11 CSJ:37

2. Virchow JC, Mehta A, Ljungblad L et al. A subgroup analysis of the MONICA study; a 12-month open label study of add-on montelukast treatment in asthma patients. J Asthma 2010;47:986-993

MT: Montelukast, FCT: Film coated tablet, LC MS/MS: Liquid chromatography-mass spectrometry ICS: Inhaled corticosteroid, LABA: Long acting beta agonist. SABA: Short acting beta agonist, ACT: Asthma control test mini-AQLA: Mini Asthma quality of life questionnaire