

A MULTICENTER, OBSERVATIONAL, PROSPECTIVE STUDY OF THE EFFECTIVENESS OF SWITCHING FROM BUDESONIDE/FORMOTEROL TURBUHALER® TO BUDESONIDE/FORMOTEROL EASYHALER®

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Abstract. *Introduction:* In real-life practice, asthma remains poorly controlled, with a considerable burden on patients' quality of life. Budesonide/formoterol (B/F) Easyhaler® has demonstrated similar dose consistency, therapeutic equivalence, and equivalent bronchodilator efficacy to B/F Turbuhaler®, but no real-life comparisons are yet available in patients switching from B/F Turbuhaler® to B/F Easyhaler®. *The primary objective* of this real-life, non-interventional, observational study was to show non-inferiority of asthma control when adult patients in Swedish primary care with persistent asthma switched from B/F Turbuhaler® to B/F Easyhaler®. *Methods:* At visit 1, baseline demographic and endpoint data were recorded, and eligible patients switched to B/F Easyhaler®. The study comprised a control visit (visit 2) and a concluding examination (visit 3) after 12 weeks. Asthma control was assessed using the Asthma Control Test (ACT). The mini-Asthma Quality of Life Questionnaire (AQLQ) and lung function test were performed, and participants and investigators answered questionnaires about ease-of-use and teaching. A total of 117 patients were enrolled in the on-treatment population; 81 (64.8 %) were female. *Results:* At visit 3, B/F Easyhaler® demonstrated non-inferiority to B/F Turbuhaler®; the mean difference in change from baseline ACT was statistically significant (18.9 vs. 20.7, respectively; $p < 0.0001$) and met the non-inferiority criteria of B/F Easyhaler® being greater than — 1.5 points versus the reference product. Asthma was well controlled in 62 (53.0 %) patients at baseline, increasing to 83 patients (70.9 %) at visit 3. Patients experienced statistically significant improvements in mini-AQLQ score after B/F Easyhaler® treatment and lung function remained stable across the treatment period. B/F Easyhaler® was easy to learn and prepare for use. *Conclusion:* This real-life, non-interventional, non-inferiority study in adults with persist asthma demonstrates equivalent or better disease control when patients switch from B/F Turbuhaler® to B/F Easyhaler®. A further study with direct comparison between treatments could add to the understanding of inhaler switch.

Key words: asthma, asthma control, inhaler technique, inhaler preference, inhaler switch, Budesonide/Formoterol Turbuhaler, Budesonide/Formoterol Easyhaler.

Переклад з англійської

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