

ORIGINAL ARTICLE

Long-term safety of mometasone furoate/formoterol combination for treatment of patients with persistent asthma

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Objective: The combination of inhaled corticosteroid (ICS) and long-acting β_2 -agonist is recommended for treatment of patients with persistent asthma inadequately controlled on ICS monotherapy. This study was conducted to evaluate the long-term safety of mometasone furoate/formoterol (MF/F) administered through metered-dose inhaler (MDI) in patients with persistent asthma previously on medium- to high-dose ICS. **Methods:** This was a 52-week, randomized, multicenter, parallel-group, open-label, evaluator-blinded study. At baseline, 404 patients (aged ≥ 12 years) were stratified according to their previous ICS dose (medium or high), then randomized 2:1 to receive twice-daily treatment of MF/F (200/10 or 400/10 μg) or fluticasone propionate/salmeterol (FP/S; 250/50 or 500/50 μg). The primary endpoint was the number and percentage of patients reporting any adverse event (AE). Additional safety evaluations included plasma cortisol 24-hour area under the curve ($\text{AUC}_{0-24\text{h}}$) and ocular changes. Pulmonary function, asthma symptoms, and use of rescue medication were monitored. **Results:** The incidence of ≥ 1 treatment-emergent AE was similar across treatment groups (MF/F 200/10 μg , 77.3% [$n = 109$]; FP/S 250/50 μg , 82.4% [$n = 56$]; MF/F 400/10 μg , 79.2% [$n = 103$]; FP/S 500/50 μg , 76.9% [$n = 50$]). Rates of treatment-related AEs were also similar across treatment groups (MF/F 200/10 μg , 28.4%; FP/S 250/50 μg , 23.5%; MF/F 400/10 μg , 23.1%; FP/S 500/50 μg , 20.0%). Headache (3.7%) and dysphonia (2.7%) were the most common treatment-related AEs overall. The nature and frequency of AEs and the decreases in plasma cortisol $\text{AUC}_{0-24\text{h}}$ observed with MF/F treatment were similar to those observed with FP/S treatment. Ocular events were rare (2–6% overall incidence among treatment groups); in particular, no posterior subcapsular cataracts were reported. Only three patients discontinued the study because of treatment-related ocular AEs (two for lens disorders in the MF/F 400/10 μg group; one for reduced visual acuity in the FP/S 250/50 μg group) and no asthma-related deaths occurred. Furthermore, MF/F showed numerical improvement in lung function and clinical benefits by reducing asthma symptoms and rescue medication use. **Conclusions:** One-year treatment with the new combination therapies – twice-daily MF/F-MDI 200/10 and 400/10 μg – is safe and well tolerated in patients with persistent asthma.