LONG-TERM SAFETY AND EFFICACY OF FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE COMBINATION THERAPY IN PATIENTS WITH ASTHMA

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Aim: The ICS fluticasone (FLUT) has been combined with the LABA formoterol (FORM) in a single inhaler (FLUT/FORM; flutiform®) for the maintenance treatment of asthma. The aim of this study was to assess the long-term safety and efficacy of FLUT/FORM.

Methods: In this open-label continuation study, 280 patients (aged ≥12 years) with asthma (baseline forced expiratory volume in 1 second [FEV1] % predicted 40–80%) who had completed 12 weeks’ treatment with FLUT/FORM 250/10 μg or FLUT 250 μg b.i.d. received FLUT/FORM 250/10 μg b.i.d. for ≤60 weeks. Lung function was assessed pre-dose and at 5, 15, 30 minutes, 2 and 4 hours post-dose on day 1 and at weeks 2, 12, 24, 36, 48 and 60.

Results: The most common adverse events (AE) were nasopharyngitis (19.6%), pharyngitis (10.7%), rhinitis (8.2%), bronchitis and headache (both 7.1%). No drug-related serious AEs were reported. The incidence of severe exacerbations (asthma deterioration requiring additional therapy [e.g. systemic steroids], or A&E visit or hospitalization) was low (2.1%, n=6); mean time to onset of severe exacerbation was 237 days (range, 37–413). Increases from baseline in FEV1, FEV1 % predicted and forced vital capacity (FVC) were observed at every assessment time point from day 1; these improvements were sustained over 60 weeks (Table).

Conclusion: FLUT/FORM is generally well tolerated and provides clinically relevant, sustained improvements in lung function during long-term therapy.

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