Effect of mometasone furoate/formoterol combination therapy on nocturnal awakenings in subjects with persistent asthma

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Objective
We characterized the effect of mometasone furoate/formoterol (MF/F) treatment on nocturnal awakenings requiring rescue-medication (SABA) use in three Phase III efficacy trials (baseline=awakenings in wk prior to first dose; endpoint=awakenings across entire treatment period).

Methods
Subjects were asthmatics previously using low- (n=746), medium- (n=781) or high-dose (n=728) inhaled corticosteroids ICS. Low-dose subjects were randomized to 26-wk treatment with MF/F 100/10μg, MF 100μg, F 10μg, or placebo; medium-dose subjects to 26-wk treatment with MF/F 200/10μg, MF 200μg, F 10μg, or placebo; high-dose subjects to 12-wk treatment with MF/F 400/10μg, MF/F 200/10μg, or MF 400μg. All treatments were delivered twice-daily via metered-dose inhaler.

Results
Baseline awakenings ranged from 0.84–1.05 (MF/F 100/10μg study), 1.05–1.26 (MF/F 200/10μg study), and 1.33–1.61 nights/wk (MF/F 400/10μg and 200/10μg study). Nocturnal awakenings were reduced by MF/F 100/10μg=−0.42, MF 100μg=−0.21, F 10μg=−0.21, and placebo=0.14 nights/wk; changes in the other placebo-controlled study were MF/F 200/10μg=−0.56, MF 200μg=−0.35, F 10μg=+0.07 and placebo=0.00 night/wk, respectively. In both of these studies MF/F was superior to placebo (P<.001) and F (P=.035); MF was also superior to F and placebo. In the non-placebo controlled study, awakenings were reduced by −0.70, −0.70 and −0.35 nights/week by MF/F 200/10μg, MF/F 400/10μg and MF 400μg, respectively; both MF/F treatments were superior to MF (P≤.006).

Conclusions
Both MF/F and MF significantly reduced nocturnal-awakenings compared with F and placebo. Both doses of MF/F were superior to MF in the non-placebo controlled study.

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