

Efficacy and Safety of Crisaborole in Patients With Mild-to-Moderate Atopic Dermatitis With and Without Comorbid Allergies or Asthma

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Background: Crisaborole ointment, 2%, is a nonsteroidal anti-inflammatory phosphodiesterase 4 inhibitor for treatment of mild-to-moderate atopic dermatitis (AD). This post hoc pooled analysis of the phase 3 studies CrisADe CORE 1 (Clinicaltrials.gov identifier: NCT02118766) and CORE 2 (NCT02118792) examined the efficacy and safety of crisaborole in patients with mild-to-moderate AD with or without comorbid asthma/allergies.

Methods: Patients aged ≥ 2 years with mild-to-moderate AD were randomly assigned 2:1 to receive twice-daily crisaborole or vehicle for 28 days. Outcomes were Investigator's Static Global Assessment (ISGA) success (clear [0] or almost clear [1] with a ≥ 2 -grade improvement from baseline) and ISGA clear/almost clear at day 29. Patients were stratified by history of asthma/allergies (which included but was not limited to allergic rhinitis, food, and other allergies).

Results: Crisaborole and vehicle were received by 585 vs 304 patients with asthma/allergies (mean age, 12.4 vs 12.1 years; moderate disease, 63.6% vs 66.1%) and by 431 vs 202 without asthma/allergies (mean age, 12.2 vs 12.1 years; moderate disease, 58.2% vs 55.5%). ISGA success rate (95% CI) at day 29 was 29.4% (25.5%-33.3%) vs 20.1% (15.3%-24.9%) in patients with asthma/allergies (difference, $P=0.003$) and 35.8% (31.1%-40.5%) vs 24.6% (18.1%-31.0%) in patients without asthma/allergies (difference, $P=0.006$). Rate of ISGA clear or almost clear at day 29 was 48.4% (44.1%-52.8%) vs 32.0% (26.5%-37.5%) with asthma/allergies (difference,

$P < 0.0001$) and 52.4% (47.6%-57.3%) vs 40.6% (32.4%-48.7%) without asthma/allergies (difference, $P = 0.014$). No new safety concerns were identified.

Conclusion: Crisaborole is efficacious and safe in treating patients with mild-to-moderate AD regardless of a history of asthma/allergies.

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