

Efficacy and Safety Trends With Continuous Long-Term Use of Crisaborole Ointment, 2%, in Patients With Mild-To-Moderate Atopic Dermatitis

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Background: Atopic dermatitis (AD) is a chronic inflammatory skin disease that often requires long-term treatment. Crisaborole significantly improved global signs and symptoms of AD in phase 3 studies. Here, the efficacy and safety of continuous long-term use of crisaborole in patients with mild-to-moderate AD based on a post hoc analysis of a 48-week, phase 3, open-label, extension study are reported.

Objective: To assess the efficacy and safety of crisaborole for continuous, long-term use in patients aged ≥ 2 years with mild-to-moderate AD.

Methods: All patients received crisaborole initially. Patients with Investigator's Static Global Assessment (ISGA) 0 (clear)/1 (almost clear) at the end of a 28-day cycle did not receive crisaborole for the next 28-day cycle (off-treatment). Patients with ISGA ≥ 2 (mild) received crisaborole for the next 28-day cycle (on-treatment). Patients were stratified by number of initial consecutive 28-day cycles of crisaborole received.

Results: 418 patients were included in exclusive cohorts (1 on-treatment cycle, n=133; 2 consecutive on-treatment cycles, n=106; 3 consecutive on-treatment cycles, n=106; 4 consecutive on-treatment cycles, n=73). In all groups, <3% of patients discontinued treatment during initial consecutive on-treatment cycles. After 1-4 initial consecutive on-treatment cycles, 77.6%, 76.3%, 59.4%, and 43.1% of patients achieved ISGA 0/1, respectively. Of these, 51.0%, 36.7%, 35.6%, and 36.2% maintained ISGA 0/1 at the end of the next 28-day cycle while off treatment. Incidences of treatment-related adverse events (AEs) were 4.5%, 4.7%, 3.8%, and 1.4% for patients receiving 1-4 consecutive on-treatment cycles. One patient discontinued due to AEs.

Conclusion: Continuous long-term treatment with crisaborole beyond 28 days may be necessary to maintain control of AD symptoms in some patients with mild-to-moderate AD. Continuous, long-term crisaborole was well tolerated.

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