Long-term safety and efficacy of clascoterone cream 1% in patients ≥12 years old with acne vulgaris

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Background: Clascoterone cream 1% is approved for the treatment of acne vulgaris in patients aged ≥12 years based on results in two 12-week, randomized, double-blind, vehicle-controlled, Phase 3 studies in patients with moderate-to-severe acne. Patients who completed one of these pivotal studies could enter an open-label long-term extension study and receive treatment for up to 9 additional months. Long-term safety and efficacy of clascoterone for up to 12 months in patients aged ≥12 years from the extension study are presented.

Methods: All patients who continued into the open-label, long-term extension study (NCT02682264) applied clascoterone twice daily to the entire face and, if desired, any truncal acne, for up to 9 months. Patients achieving Investigator's Global Assessment score of 0 or 1 (IGA 0/1) could stop treatment and resume if/when acne worsened. Safety was assessed from treatment-emergent adverse events (TEAEs) and local skin reactions (LSRs [telangiectasia, skin atrophy, striae rubrae, erythema, edema, scaling/dryness, stinging/burning, and pruritus]) in all treated patients. Efficacy was assessed from percentage of patients with IGA 0/1 among those who completed the extension study without significant protocol deviations (per-protocol [PP] population).

Results: Of 598 patients treated in the extension study, 108 (18.1%) experienced 187 TEAEs, with similar frequency between patients previously treated with vehicle (52/287 [18.1%]) vs clascoterone (56/311 [18.0%]). Frequency of LSRs was low throughout the study. Percentage of PP patients with facial and truncal IGA 0/1 increased over time to 48.9% (156/319) and 52.4% (65/124), respectively, at end of study and was greatest in patients applying clascoterone for 12 months (face, 67/119 [56.3%]).

Conclusion: Clascoterone cream 1% maintained a favorable safety and efficacy profile for up to 12 months in patients aged ≥12 years.

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