Clinical Evaluation of a 4% Hydroquinone plus 1% Retinol Treatment Regimen for Improving Melasma and Photodamage in Fitzpatrick Skin Types III-VI

Patricia K Farris, MD,1 Laurence Dryer, PhD2
1Department of Dermatology, Tulane University School of Medicine, New Orleans, LA 70112; 2Research and Development Department, Valeant Pharmaceuticals North America LLC, Irvine CA 92618.

Abstract
The benefits of combined therapy with hydroquinone for melasma and retinoids for photodamage are well established. Here we report results of a hydroquinone-observed regimen designed for melasma treatment combined with a cosmeceutical retinoid in an industry-sponsored, single-center, randomized, investigator-blinded, parallel-arm study for the treatment of melasma and photodamage in Fitzpatrick Skin Types III-VI.

Methods

- **Study:** Single-center, investigator-blinded study in adult females with mild-to-moderate epidermal melasma and photodamage
- **Treatment:** 4% hydroquinone skin care system plus 1% retinol cream for 24 weeks
- **Efficacy assessments:** improvements in melasma severity, pigmentation intensity, photodamage, patient satisfaction
- **Tolerability assessments:** erythema, dryness, peeling, burning, and stinging

Results

- Improvements relative to baseline were significant from week 4 onwards for pigmentation intensity (P<.001), MASI (P=.003) and integrated photodamage (P=.044), and from week 8 for melasma severity (P<.001). By week 24, significant reductions in melasma severity (37.1%), pigmentation intensity (47.7%), MASI (64.7%) and integrated photodamage (42.4%) scores were reported (all P<.001).
- Overall improvement in melasma was adjudged to be ‘marked’ (51%-75%) by week 24. The majority of patients reported favorable responses to treatment efficacy and general skin condition. Representative patient examples are showing benefits in melasma and photodamage as shown in Figure 2.

- Individual photodamage parameters improved significantly from week 4 onwards for mottled hyperpigmentation (P<.001), and from week 8 for lentigines, tactile roughness, bumpy fine wrinkling (all P<.001), and crepiness (P<.001). Improvement in coarse wrinkling was significant from week 18 (P=0.002).
- By week 24, significant reductions in lentigines (56.1%), tactile roughness (48.8%), bumpy (40.3%) mottled hyperpigmentation (46.3%), fine wrinkling (47.8%), coarse wrinkling (20.0%) and crepiness (54.1%) scores were reported (all P<.001).
- No patient discontinued due to lack of efficacy or treatment-related AEs. One patient (2.8%) reported severe cutaneous incidenility (dryness and peeling from week 4).

Conclusion

- 4% hydroquinone skin care system plus 1% retinol cream achieves significant reductions in melasma severity and pigmentation intensity
- There was also significant improvement in photodamage, with all individual parameters including coarse wrinkling significantly improved by week 24
- The treatment was generally well tolerated

**Figure 1:** Mean Percent Change in Efficacy Parameters from Baseline (ITT population Week 4-24, N=33)

**Figure 2:** Representative Patient Examples Showing Improvements in Melasma Severity and Photodamage from Baseline to Week 18 and 24

**Figure 3:** Mean Percent Change in Individual Photodamage Parameters from Baseline (ITT population Week 4-24, N=33)

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