

## Dr. Mark Rubin on the safety of Fluocinolone Acetonide (0.01%)

There have been several published papers showing that the addition of retinoids to products containing topical steroids reduces the risk of steroid induced skin atrophy. With the approval and use of the prescription bleaching product, Triluma (which contains 4% Hydroquinone, Fluocinolone Acetonide 0.01% and Tretinoin 0.05%), even more data has been presented showing the safety of long-term use of Fluocinolone Acetonide when used in conjunction with a retinoid. In the paper by Tork, HM et al in *Cutis* 2005, Jan: 75(1) 57-62; they followed 228 patients who used Triluma nightly for at between 6-12 months. There were no reports of skin atrophy.

### Additional References:

[Am J Dermatopathol. 2009 Dec;31\(8\):794-8](#)

A histological examination for skin atrophy after 6 months of treatment with fluocinolone acetonide 0.01%, hydroquinone 4%, and tretinoin 0.05% cream.

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### Abstract

Melasma is a common disorder affecting a significant percentage of the population, particularly those with skin of color. Therapy with hydroquinone, a depigmenting agent, as a single agent or in combination with other agents has been used with variable success. A triple-combination (TC) cream combining hydroquinone 4% with tretinoin 0.05% and fluocinolone acetonide 0.01% was developed for the treatment of melasma. We studied the use of TC cream for 24 weeks and had tissue samples for all time points in 62 patients with moderate to severe melasma. The atrophogenic potential of TC cream was evaluated through serial histopathologic examination of skin biopsies. No statistically significant histopathologic signs of atrophy of the epidermis or dermis were noted at any time point throughout the study. There was a marked reduction in epidermal melanin in treated subjects; however, we did not observe any significant difference in baseline and treated samples in the amount of perivascular inflammatory infiltrate, dermal mucin, keratinocyte and melanocyte atypia, or mast cells, consistent with findings of previous studies where topical retinoids were used. An increase in the mean number of blood vessels per square millimeter of tissue was observed in 2 study cohorts between baseline and week 24. These results suggest that the risk of skin atrophy with 24-week use of TC cream for the treatment of melasma is very low.

**Mark G. Rubin, MD**, is a board-certified dermatologist, currently practicing at the Lasky Clinic in Beverly Hills which specializes in cosmetic dermatology. In addition, Dr. Rubin is an Assistant Clinical Professor of Dermatology at the University of California, San Diego.

Dr. Rubin is a specialist in skin rejuvenation and has written multiple papers, book chapters and a textbook on this subject. He has also personally trained over 600 physicians in his techniques. He is an international lecturer and has presented his ideas and research in more than ten countries.

In addition to his work with patients, Dr. Rubin also performs clinical research projects, and works as a consultant for various skin care and medical device companies.