

# CLINICAL EVALUATION OF A DEPIGMENTARY CREAM (UNITONE 4) IN MELASMA

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## Background:

Melasma is an acquired symmetric hypermelanosis of the face characterized by irregular light to gray brown macules and patches involving sun exposed areas of skin. Although the cause is genetic, the condition is aggravated with sunlight and with inopportune application of some cosmetic especially traditional cosmetics. Numerous depigmenting topicals are available today but cosmetic results are disappointing. Many modalities of treatment are available but none is satisfactory.

We have tested the depigmenting cream UNITONE 4 (combination of hydroquinone (2%), kojic acid, citric acid, glycolic acid) in the treatment of melasma of the face.

## Materials and Methods:

49 patients (38 women, 11 male) with melasma were included in the study. The women with hormonal treatment, who have tried a topical treatment in the last three months were excluded.

A skin biopsy has been done in some cases to eliminate an actinic lichen. It is a double blind study the vehicle serving as placebo. The cream was applied in the evening for 3-months. The clinical examination assesses the intensity and the area pigmentation according to a VAS (Visual Analog Scale). The patient rated the same items with the same Visual scale.

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The efficiency and any adverse effects of the cream were recorded at days 0, 30, 60 and 90. All assessments were carried out by physicians and patients independently.

## Results:

Of the 49 patients (38 women and 11 men) included in this study n, 7 (4 women and 3 men) did not keep their appointments and were not included in the analysis of results.

The mean age of the patients was 31, 3+3, 4 years  
And melasma duration was: 28, 9+6, 7 months

The clinical evaluation and the patient's own evaluation of the color and the sizes of the pigmented areas showed a significant improvement with UNITONE 4 versus vehicle.

	Vehicle	Unitone 4
Day 30	+ 10, 0	- 12, 3
Day 60	- 8	- 38, 9
Day 90	- 15=	- 65, 2

Tableau I: Color Visual Analog Scale score evolution according to visits and treatment. (p<0,001)

	Vehicle	Unitone 4
Day 30	+ 23, 1	+ 15, 2
Day 60	+ 14, 6	- 21, 7
Day 90	+ 9, 0	- 38, 9

Tableau II: Area Visual Analog Scale score evolution according to visits and treatment. (p<0.001)

On day 90, the results were 71.8% improved with Unitone 4 and 19.2% with vehicle.

## Discussion and Conclusion:

- Unitone 4 cream showed a good rate of improvement and was well tolerated in 89.2% of patients
- The discrete improvement with vehicle may be explained by seasonal factor
- (melasma is less evident in autumn and winter) and by the moisturizing effect of the vehicle



Fig. 1 Melasma in man before treatment.



Fig. 2 After treatment.

- The few adverse reactions seen especially in the first month of treatment were: sensory symptoms such as burning and itching and were probably related to the acidic properties of kojic and glycolic acids.
- Apart from the genetic predisposition (phototype), the main factor was the use of traditional cosmetic products.
- Melasma continue to be a difficult problem. Although the main cause is genetic, the condition is aggravated with sunlight, birth control pills and pregnancy. Although hydroquinone is effective and has been available for years, a new product, kojic acid, has the advantage of being pharmaceutically more stable and also a tyrosinase inhibitor.
- Both glycolic acid/kojic acid and glycolic acid/hydroquinone topical skin care products are highly effective in reducing the pigment in melasma patients(1).
- A cream containing 10% glycolic acid and 2% hydroquinone improved melasma and fine facial wrinkling in Asian women. In combination with
- Glycolic acid peels at 3-week intervals the lightening of melasma is subjectively much better (2).

- Superficial peels hasten the effects of topical therapy in melasma. Wood's light examination did not help predict response to treatment (3).

**References:**

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