

A VEHICLE CONTROLLED, DOUBLE-BLIND STUDY OF A NEW DEPIGMENTING EMULSION IN MELASMA PATIENTS

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INTRODUCTION

Hyperpigmentary disorders such as melasma are often difficult to treat. There are many modalities of treatment i.e chemical compounds or physical therapies, to reduce skin pigmentation, but none provide complete satisfaction. The aim of this trial was to compare the efficacy, tolerance and acceptability of a new depigmenting emulsion versus its vehicle in melasma.

PATIENTS AND METHODS

A comparative intra-individual randomized double-blind vehicle controlled clinical study was conducted on a depigmenting emulsion containing vitamine PP, licorice extract, anti-oxidants and soothing ingredients, alpha and beta-hydroxy-acids, associated with Uriage Thermal Water. Patients affected by light to moderate forms of epidermal melasma, MASI (Melasma Area Severity Index) score > 5, were included. They were assigned to randomly apply the depigmenting cream and its vehicle on the left or right hemi-face twice a day for 12 weeks.

A broad-spectrum sunscreen (SPF50+, UVA+, Laboratoires Dermatologiques d'Uriage) was then applied to the face, 15 minutes after verum or vehicle applications.

Efficacy assessments were made of chromametry measurements (CR300®, Minolta, Japan) pigmentation clinical score (visual analogical scale from 0 to 10), standardized photographs and global efficacy score. Skin tolerance (4-point scale) and patients' self-assessment were also performed. Evaluations were made at baseline, weeks 6 and 12.

The study was conducted in South of France, during spring and summer time.

STATISTICAL ANALYSIS

Comparisons between baseline and each follow-up visit (within group differences) were performed using a paired Student or Wilcoxon tests depending of the type of distribution.

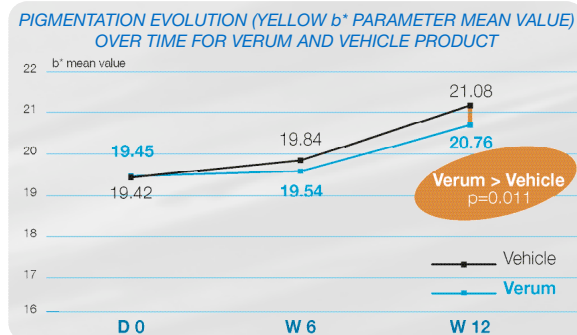
Statistical tests were interpreted at a 5% significance level.

RESULTS

17 female aged from 30 to 49 years (mean 38±5 years), with Fitzpatrick's skin types III and IV were included with clinical diagnosis of a bilateral epidermal melasma (MASI = 11.5 ± 7.6).

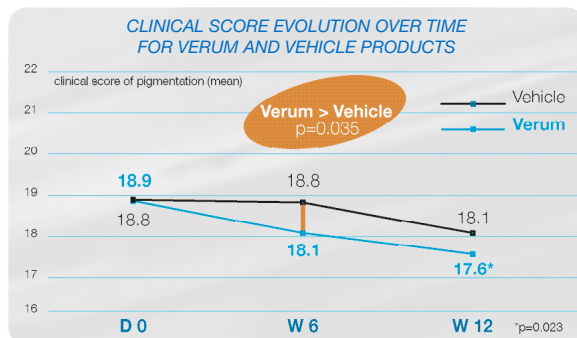
● Colorimetry measurements

The depigmenting emulsion produced statistically improvement in colorimetric measurements: significantly lower b* values at week 12 for the verum compared with vehicle (p=0.011). The skin was then significantly less pigmented after 12 weeks of treatment with verum compared to vehicle. For each product a season effect (b* parameter increase) was noted between week 12 and baseline.



● Pigmentation clinical score and global evaluation score

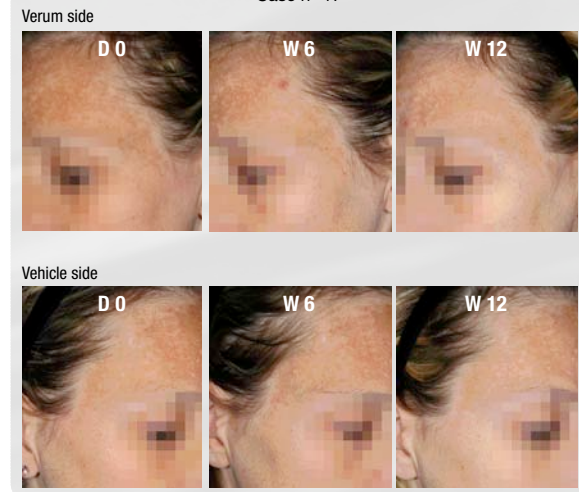
The clinical score of pigmentation assessed of each test site (forehead, cheek and chin). Showed clinical improvement compared with baseline only for verum (p=0.023) at week 12. A significant difference in pigmentation intensity was showed between both products (p=0.035) at week 6 with a lower pigmentation global score for the active product.



● Global efficacy

At week 12, light to marked improvement was achieved in 59% and 24% of the cases, respectively for verum and vehicle, as judged by the patients.

ILLUSTRATION OF EFFICACY BY USING CROSS-POLARIZED LIGHT



● Skin tolerance

Skin tolerance was considered as "excellent" or "good" in 100% of the cases, either for active or vehicle products, as assessed by the dermatologist.

No reaction of intolerance to the tested products was reported in the study.

● Acceptability and efficacy self-evaluation

Patients' self-assessment showed good similar cosmetic qualities for both products but a better efficacy for the verum.

SELF-EVALUATION : ACCEPTABILITY AND EFFICACY

	Verum	Vehicle
Rapid penetration	71%	82%
Melasma severity decrease	42%	12%

CONCLUSION

This double-blind clinical study showed that this new depigmenting formulation is effective to reduce significantly facial hyperpigmented spots linked to melasma (not significant pigmentation decrease for the vehicle). The acceptability was judged satisfactory and the tolerance of the product was excellent to good during the 12-week study.