

Clinical Efficacy and Skin Compatibility of Eucerin® Anti-Age Anti-Pigment Fluid, a novel Anti-Age Face Care Fluid containing Dioic Acid

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Abstract

Hyperpigmentation skin disorders like melasma can have a severe impact on patients' wellbeing and quality of life. They can be induced by functional disturbances of formation, maturation, secretion, or transport of melanosomes. UV-irradiation intensifies the clinical picture. Therefore, the application of depigmenting formulations with effective UV-filtering properties is helpful in preventing and reducing skin discoloration and improving the quality of life.

Dioic acid is a derivative of oleic acid and acts in the melanocyte by slowing down the melanin synthesis and thus reducing the secretion of melanosomes into keratinocytes. Its efficacy has been proven in various in-vitro and in-vivo experiments.

In the present clinical study, a formulation containing dioic acid plus UV filters with high UVA- protective efficacy (Eucerin® Anti-Age Anti-Pigment Fluid) was investigated for efficacy and skin tolerability in melasma. 13 female patients applied the fluid to facial skin twice daily for 12 weeks. Evaluation of four areas of the face (forehead, right malar area, left malar area and chin) was performed according to the Melasma Area and Severity Index (MASI) in comparison to baseline. In addition, colorimetry and photographs were taken at each site of the face at start, after 4 and 8 weeks and at the end of the study. Furthermore, patients were interviewed with respect to their quality of life using a standardized questionnaire at start and end of the application period and the patients assessed product performance in an interview after finishing the study. The results on favourable pigment reducing efficacy and skin tolerability are presented.

Introduction

Melasma is a characteristic pattern of marginated facial hyperpigmentation, occurring primarily on the forehead, cheeks, and chin in a mask like distribution (1). The pathogenesis of melasma is not fully understood, but genetic and environmental factors are thought to play a role in the development of this condition. Environmental factors include UV radiation exposure, pregnancy, oral contraceptives, oestrogen-progesterone therapies, thyroid dysfunction, cosmetics and medications (2). Although melasma is seen in both sexes and all races, women are most commonly affected, and it appears to be more prevalent in darkly pigmented races (1).

Melasma is an easily detectable disease, and women therefore often use numerous over-the-counter and prescription products in attempts to lighten or hide this condition (2). In caucasian patients, hydroquinone is the most frequently used treatment and has been used alone or in combination with corticosteroids and retinoic acid. However, hydroquinone decreases melanosome formation, increases melanosome degradation, and produces melanocyte necrosis, which bears the risk of uneven depigmentation, contact dermatitis, and ochronosis with prolonged use at high concentrations. No agent has been shown to produce significant and safe lightening of melasma (1).

Octadecene dioic acid is a naturally produced fatty acid derivative (Fig. 1), which has an inhibitory effect on the dispersion of melanin into epidermal keratinocytes (Fig. 2). Therefore this specific dioic acid is perfectly suited for reduction of hyperpigmentations. As melasma can be exacerbated by UV exposure, avoidance of sun exposure is mandatory to maintain a light and even skin colour. UVA and UVB absorbers protect from further stimulation of melanogenesis.

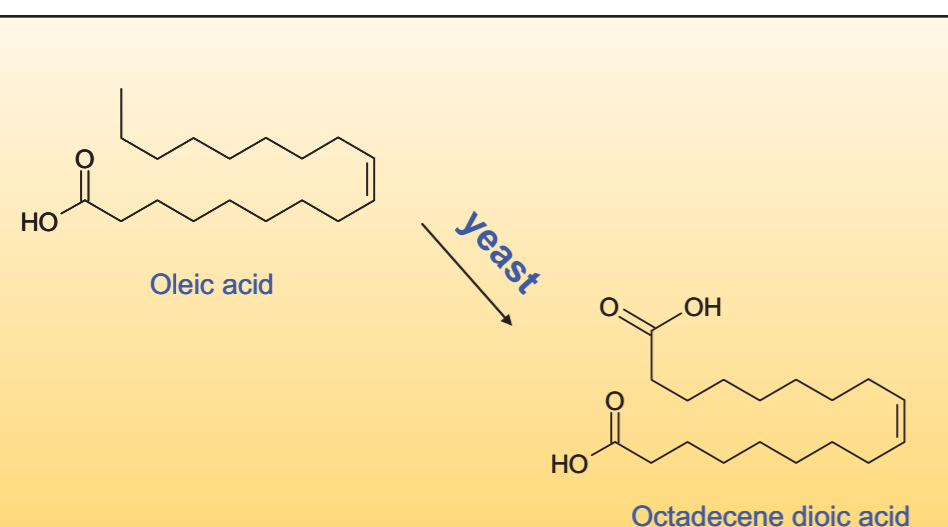


Figure 1: Dioic acid production – biotechnological process

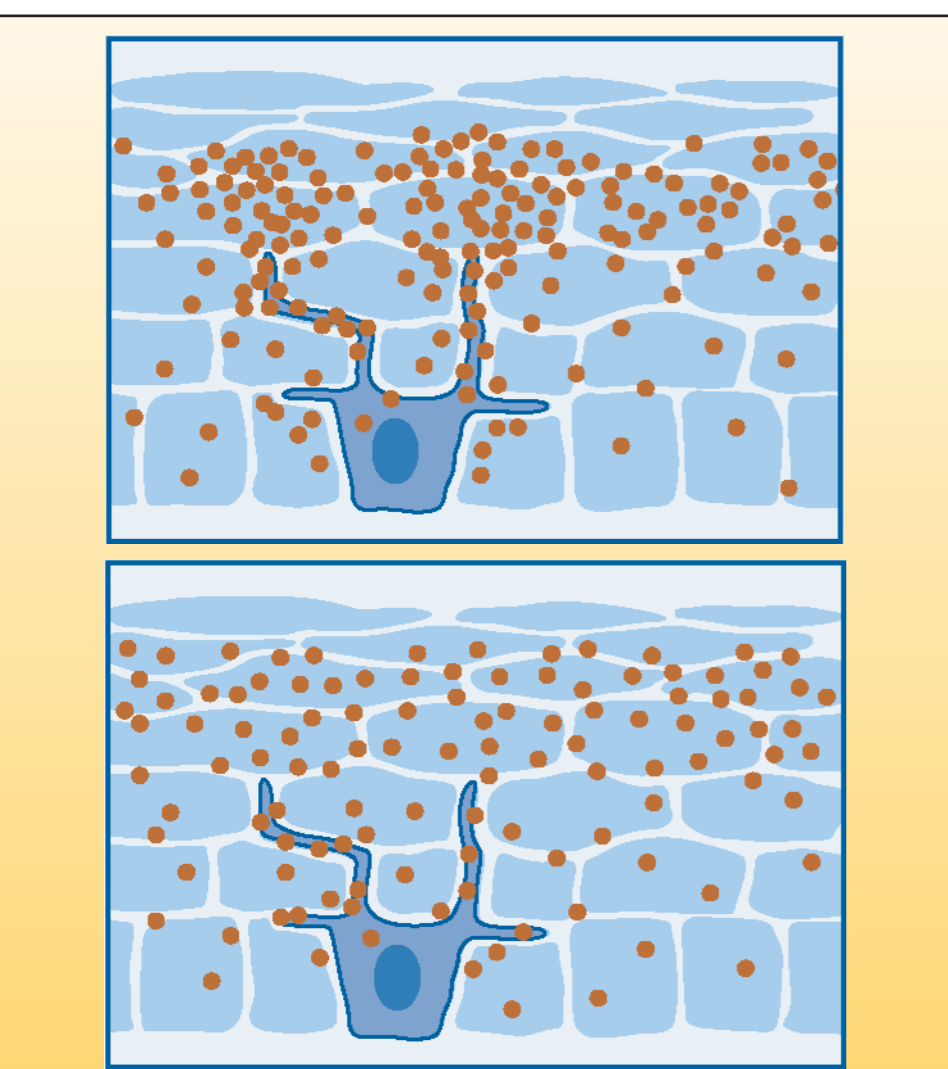


Figure 2: Melanin distribution to keratinocytes before and after application of octadecene dioic acid (schematic)

We performed a clinical study to evaluate the efficacy and tolerability of a product containing octadecene dioic acid in combination with UVA (Bis-Ethylhexyloxyphenol Methoxyphenyl Triazine) and UVB absorbers (Ethylhexyl Triazone, Phenylbenzimidazole Sulfonic Acid) as well as its effect on the quality of life of melasma patients.

Materials and Methods

Subjects

13 female patients aged over 18 years (mean = 41.1 ± 9.5 years) with actual melasma of the face were included into this open, dermatologically controlled monocentric in-use study. Exclusion criteria included the following conditions: Pregnancy or lactation, active skin disease at test area except for melasma, concomitant therapy with immunosuppressive drugs, antihistamines, antiplogistic agents, analgetics or topical medication at the test area that could interfere with the aim of the study, intensive sun exposition, UV-therapy, artificial tanning within the last 14 days prior to the start of the study.

Study preparation and application

An oil-free O/W-fluid for daily face care containing dioic acid and SPF 20 with high UVA-protection (Eucerin® Anti-Pigment Fluid) was applied to facial skin twice daily for 12 weeks according to physician's advice. The study was conducted during spring season (February until April 2004). In case of intensive UV-irradiation the patients used a standardized sunscreen product (Eucerin® Ultra Sun Protection Body and Face Cream SPF 50+) once daily instead of the original test product. The second application of the test product was continued at the respective day.

Evaluation criteria

At the beginning as well as after an application period of 4, 8 and 12 weeks, a dermatologist performed an examination of the facial skin. It was evaluated with respect to the melasma intensity according to the Melasma Area and Severity Index (MASI) in all four areas of the face (forehead, right malar, left malar, and chin) (1) and by colorimetric measurements. Furthermore, volunteers were interviewed with respect to their quality of life and subjective actual skin state using a standardized questionnaire on melasma-related disability (MELASQOL) (2) at start and at the end of the use period after 12 weeks. In addition they were interviewed with respect to product acceptance at the end of the study period.

Results

MASI

A decrease of the area extent (Fig. 3) and the MASI score (Fig. 4) was significant at all evaluated areas besides the chin. After 8 weeks and 12 weeks of treatment the MASI decreased significantly compared to the baseline as well as compared to day 29.

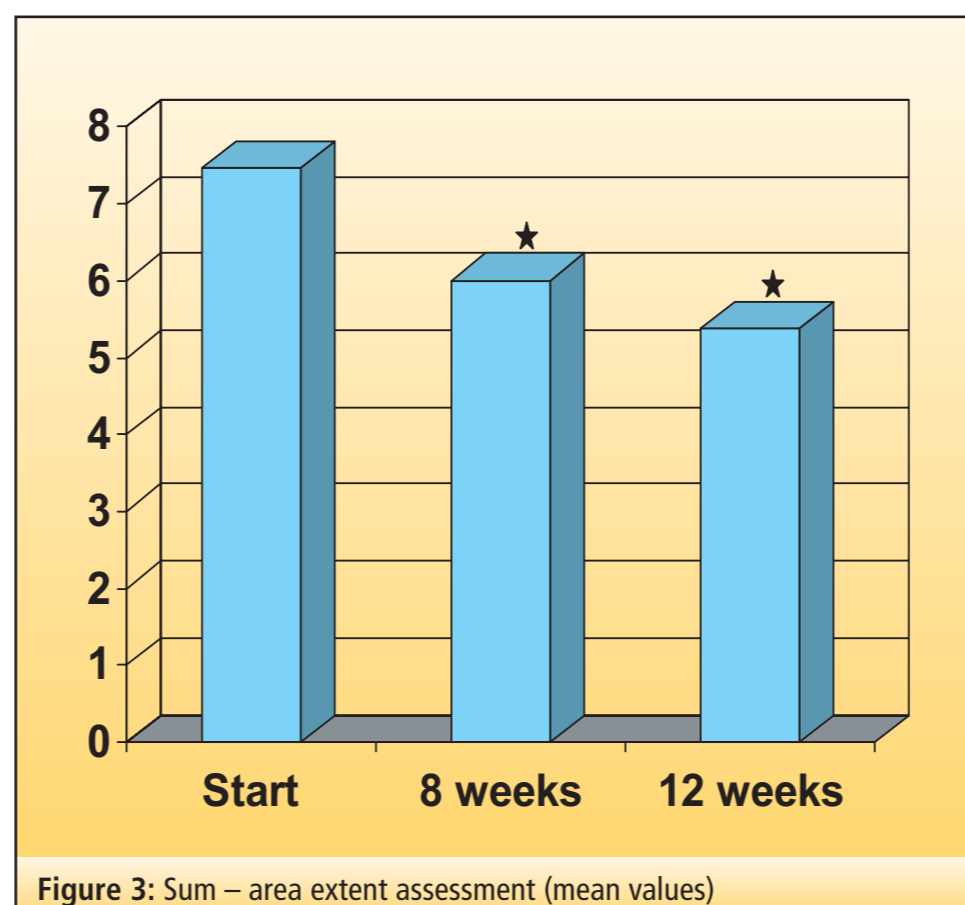


Figure 3: Sum - area extent assessment (mean values)

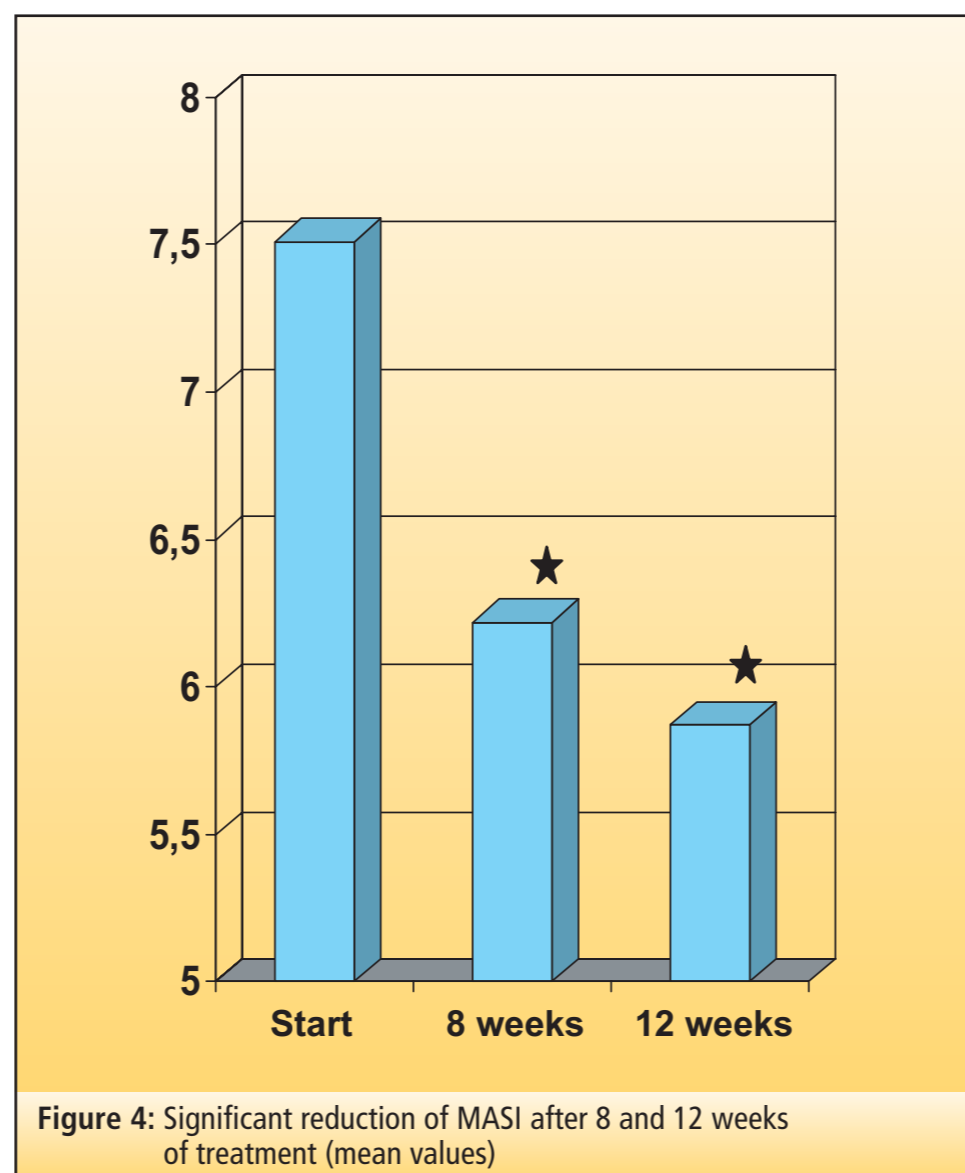


Figure 4: Significant reduction of MASI after 8 and 12 weeks of treatment (mean values)

MELASQOL

A comparison of the mean scores before and after the test period revealed an overall improvement of quality of life. Especially the burden of the volunteers by the embarrassing appearance of the skin was relieved. Furthermore the panelists had clearly less problems with the condition and appearance of the skin, the feeling of being less attractive because of skin discoloration, and with the annoyance about the condition of the skin. The changes of quality of life were significant (Fig. 5).

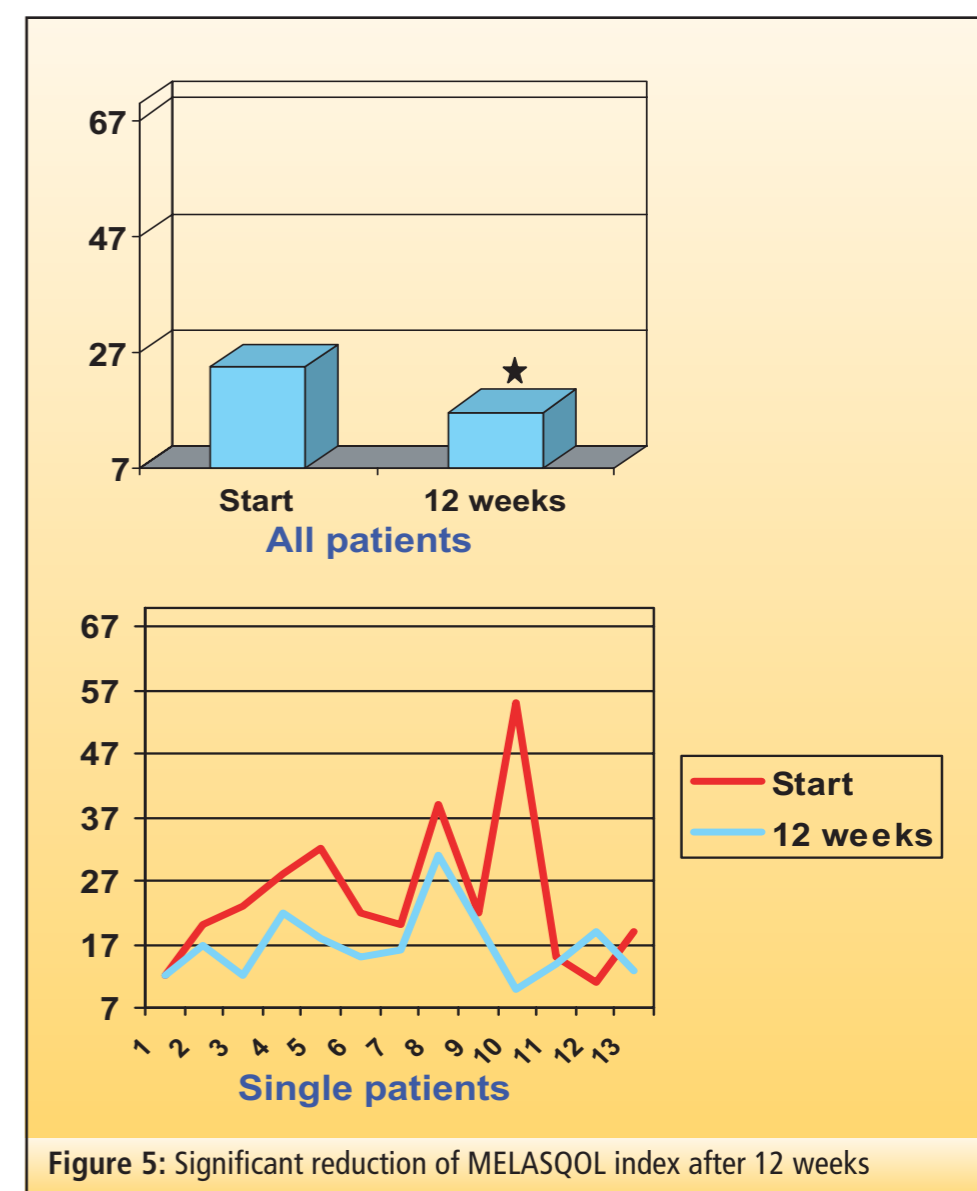


Figure 5: Significant reduction of MELASQOL index after 12 weeks

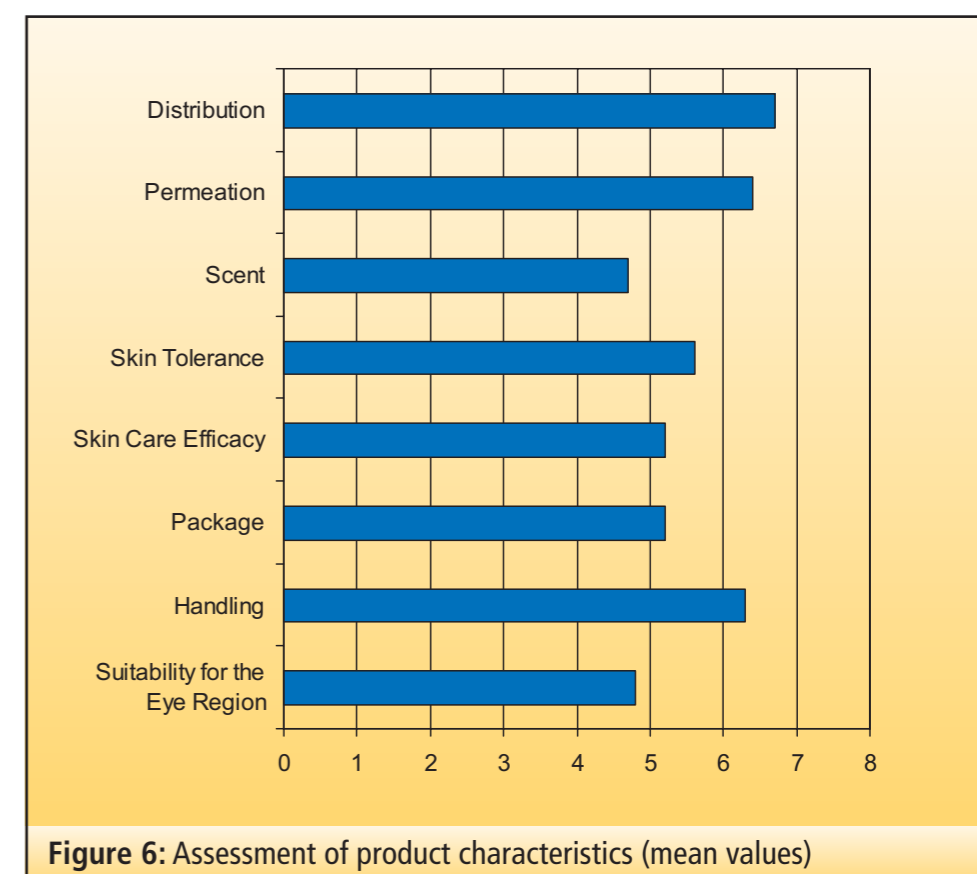


Figure 6: Assessment of product characteristics (mean values)

Assessment of product characteristics

The volunteers assessed the performance of the test product in a questionnaire by evaluating various product properties between "excellent" (note 7) and "bad" (note 1). The volunteers evaluated the distribution of the test product with the highest mean score of 6.7. A very good to excellent mean score between 6 and 7 was also given for the penetration and the handling of the test product. The skin tolerance, skin care efficacy, and the package obtained also good to very good mean scores (between 5 and 6). The scent and the suitability for the eye region were rated as good or indifferent (mean scores between 4 and 5, Fig. 6).

Skin compatibility

No increase of subjective skin reactions from the beginning to the end of the study was documented. The skin tolerability with regard to the dermatological evaluation was judged as "very good to good".

Discussion and Conclusion

The presented study underlines the efficacy and compatibility of the tested anti-pigment fluid. The dermatological assessment of the overall MASI score revealed a significant improvement of the skin discoloration. This result is of special interest because the skin discoloration normally increases in spring with cumulating UV-irradiation. The subjective evaluation of the pigment disturbance confirmed these results. To our knowledge this is the first time that the MELASQOL has been used in a face care study with melasma patients. The efficacy of the tested fluid was impressively accompanied by a significantly improved quality of life at the end of the study. Additionally, patients had not reported any side effects like itching, burning, tension and dryness during the study and the majority of volunteers were very satisfied with the properties of the test product. This outcome is remarkable because the established therapies show very often side effects like contact dermatitis (1,3,4). In the present study we could show that the Eucerin® Anti-Pigment Fluid, especially developed for hyperpigmented skin conditions of the face is excellently suited and highly tolerable for subjects with melasma and a valuable tool for dermatologists to improve their patients' quality of life.

References

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