EFFICACY OF AN ACTIVE COMPLEX ON MELANOGENESIS, UV-INDUCED INFLAMMATION, AND IN BRAZILIAN SUBJECTS SUFFERING FROM MELASMA

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INTRODUCTION & OBJECTIVES

Melasma is associated with an overactivation of tyrosinase activity, which is often characterized by persistence and recurrence, particularly due to ultraviolet (UV) rays. In fact, UV rays are responsible for inducing the activity of proinflammatory mediators, especially of prostaglandin E2 (PGE2) which are capable of hyperstimulating melanocytes. This work aims to demonstrate the efficacy of a complex of active ingredients on melanogenesis and UV induced inflammation *in vitro* and subsequently on melasma *in vivo.*

MATERIAL AND METHODS

- **Melanogenesis evaluated *in tubo* by tyrosinase activity:** measurement of tyrosine transformation into dopachrome absorbed at 490 nm.
- **UV induced inflammation measured by PGE2 *level in vitro* using ELISA:** normal human epidermal keratinocytes were pre-treated for 2 hours with the complex (*Andrographis paniculata* leaf extract, *Glycyrrhiza glabra* root extract [liquorice] and azelaic acid and niacinamide). They were then irradiated with UVA/B and incubated again for 24 hours with the active ingredients.
- ***In vivo* efficacy:** 41 Brazilian women with a mean age of 37 years and with mild to moderate melasma were included in a clinical trial. For 5 months, the subjects applied sunscreen on their faces in the morning and the product with the complex (without niacinamide) in the evening. On D0, D28, D56, D84, and D140 the investigator took standard photographs (VISIA CR®), calculated the modified MASI score and evaluated general efficacy and tolerance. On D0 and D140, subjects evaluated the impact of melasma on their quality of life (MELASQoL) as well as subjective efficacy on D140.

RESULTS

The complex significantly inhibited *in tubo* tyrosinase activity and *in vitro* PGE2 synthesis (see **Table 1**).

	Molecules	% inhibition
Tyrosinase	Complex	-81.7%***
	Kojic acid 2mM	-58.4%***
	Hydroquinone 4% 2%	-33.4%** -16.3%*
PGE2	Complex + niacinamide	-71 to 74%***
	Indomethacin 10µg/mL	-86%***

Table 1. *Evaluation of in tubo tyrosinase activity and in vitro UV-induced PGE2 (*p>0.05; **p<0.001; ***p<0.001, Student t test)*

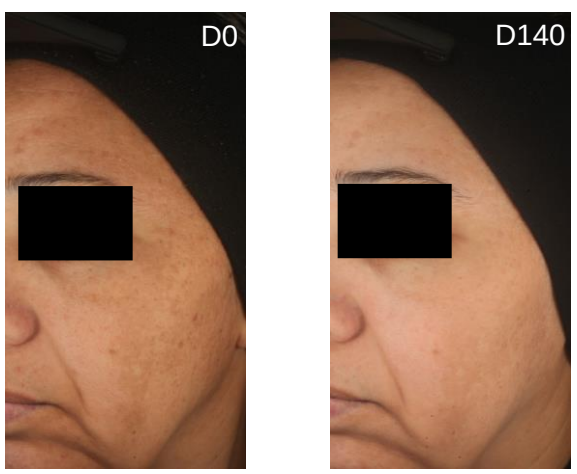
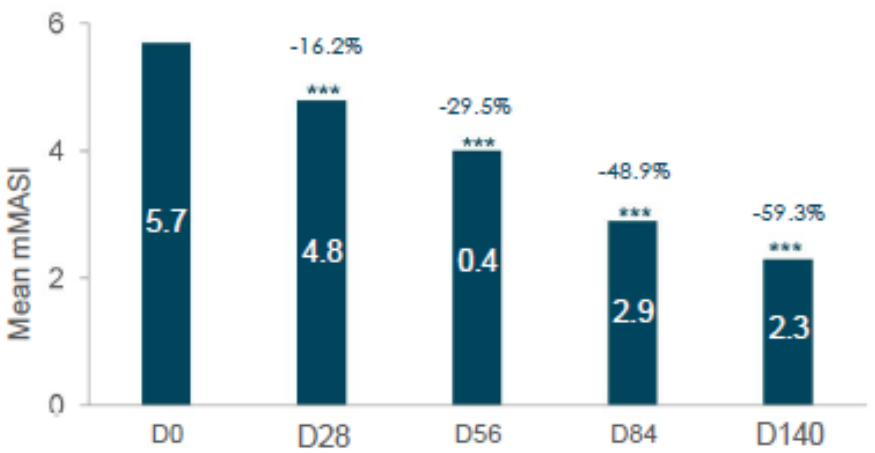


Figure 1. *Photographs of a subject on D0 and D140*

In vivo, after 28 days, the mMASI score saw a significant reduction of about 16.2% (see **Graph 1**)**,** associated with **improvement in 58.5% of subjects.** This improvement continued during the following months, with a reduction in mMASI score in all subjects on D140 (see **Figure 1**).



Graph 1. *Significant improvement in mMASI from D0 to D140 (*** p<0.001, Student t test)*

Subjects' quality of life improved on D140 with a **significant reduction of 52.6% in MELASQoL score.** In fact, subjects reported moderate to very significant efficacy overall for 90.2% of cases, and for clearing skin, uniformity, prevention of appearance of new spots and reduction of spots in 63.4% to 78.0% of cases.

Overall, the product was well tolerated by subjects. An increase in objective signs (primarily erythema) was observed in the first month of use. After 1 month and until the end of the study, no statistically significant differences were observed in objective and subjective signs between D56, D84, D140 and the initial visit.

CONCLUSION

By noticeably inhibiting tyrosinase activity and UV induction of PGE2, the product containing the complex of active ingredients reduces the severity of melasma 28 days after its application and thus improves subjects' quality of life.