EFFICACY EVALUATION OF AN AGE SPOT SERUM

Clinical evaluation

Sponsor

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Investigator

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OBJECTIVES

To evaluate, on subjects presenting first signs of hyperpigmentation due to sun exposure or age spots on the face, the efficacy of an Age Spot Serum after 7, 14 and 28 days of twice-daily use:

- **skin appearance**: evaluation of intensity and number of visible age spots by clinical score,
- spots appearance: evaluation of spots reduction using VISIA® CAS system,
- visual illustrations: macrophotographs of the face with VISIA® CAS system,
- perceived efficacy and global appreciation: subjects' answers to a subjective evaluation questionnaire.

RESULTS

Anti UV spots effect

Already from 7 days of use, the product Age Spot Serum presents a significant anti UV spot effect: UV spot count significantly decreases on the face (-29% on average on D7, -22% on D14 and -21% on D28; p<0.05). 86%, 80% and 79% of the subjects respectively on D7, D14 and D28 present a positive effect.

UV SPOTS

A significant decrease of UV spots presented an improvement of skin reactions due to sun damage

Kinetics	Δ (mean ± SEM)	Δ% of the mean	р	% subjects with the expected effect
Δ D7	-70 ± 20	-29%	0.0021	86%
Δ D14	-46 ± 19	-22%	0.0236	80%
Δ D28	-42 ± 20	-21%	0.0474	79%

Skin appearance

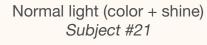
The product Age Spot Serum induced a statistically significant reduction in the intensity and number of age spots after 14 and 28 days of use:

- √ a significant decrease in the spots intensity of 16% and 24% on D14 and D28 respectively, on average. An improvement was observed in 70% of the subjects on both D14 and D28.
- √ a significant decrease in the number of spots of 9% and 14% on D14 and D28 respectively, on average. An improvement was observed in 55% of the subjects on D14 and in 65% of the subjects on D28.



Visual illustrations

Examples of photographs obtained with Age Spot Serum on subject #21. The spots become less visible, they are less numerous and the skin appear clearer, brighter and is more unified.

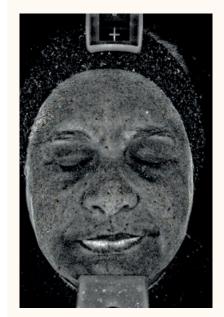




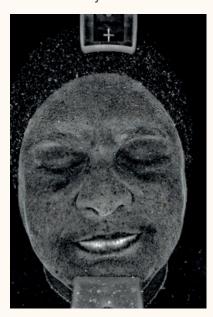




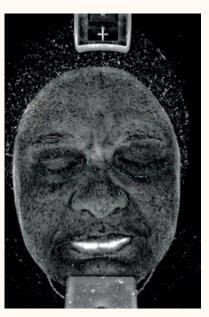
Macrophotography using the VISIA CAS System with UV spots count Subject #21







141 UV spots

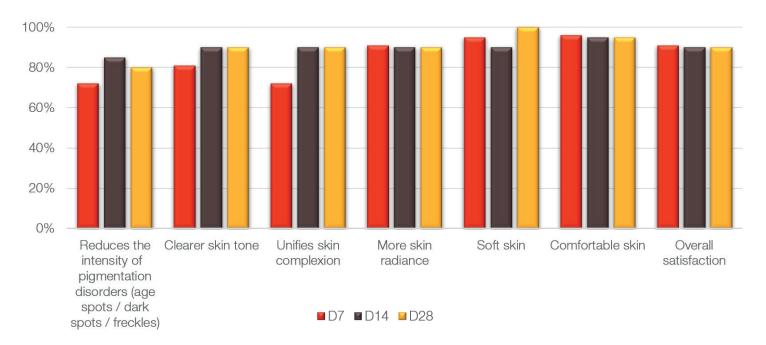


54 UV spots



Perceived efficacy and global appreciation

The subjective evaluation questionnaire performed after 7, 14 and 28 days of twice daily application of Age Spot Serum indicates that the **perceived efficacy steadily increases.**



Already after 7 days of use, 91% of the subjects observe a more skin radiance, 81% see their skin complexion clearer and 72% observe a reduction in the intensity of pigmentation disorders, a lightening of their spots and an unification of their skin complexion.

After 28 days of use, 90% judge their skin complexion brighter and more unifi ed and 80% observe a reduction in the intensity of pigmentation disorders. 100% of the subjects appreciate the product Age Spot Serum and find it pleasant to apply.

90% of the subjects would like to continue to use the serum and 85% would like to buy it.

CONCLUSION

- The product Age Spot Serum is an effective prevention of hyperpigmentation in combination with UV protection during sun exposure. Already after 7 days of twice daily use on the face, the product presents a significant anti-UV spots effect:
- √ 86% of the subjects presented an improvement of skin reaction du to sun damage on D7 with a significant decrease in the UV spots count.
- The product Age Spot Serum demonstrates a global efficacy to reduce the appearance of age spots and uneven skin tone. After 14 and 28 days of use:
- The spots are less visible and numerous
- 90% of the subjects judge their skin tone clearer and more even
- A large majority of the panel is satisfied with the serum and 90% would like to continue to use the serum. They find it efficacious on pigmentation disorders and skin complexion.



This was an open, intra-individual study; each subject was her own control.

PANEL

The study was conducted on 22 healthy women, aged between 27 and 64 (average age: 49±2 years) and presenting first signs of hyperpigmentation due to sun exposure or age spots on the face.

APPLICATION METHOD

At home: the subjects applied the product twice-daily under normal conditions of use on the whole face and neckline.

MEASUREMENT PRINCIPLES

Skin appearance

On D0 before application of the product, D7, D14 and D28 after application, the dermatologist performed clinical scoring of the skin state thanks to structured scales. The following parameters were evaluated: spots intensity from 0 (none) to 10 (very intense) and spots number from 0 (none) to 10 (very numerous).

Spots reduction

On D0 before application of the product, on D7, D14 and D28 after application, standardized pictures under multi-spectral light were taken of the full face with VISIA® CAS system (Canfield Imaging) to visualise UV spots (with ultraviolet illumination) or brown spots (using cross polarized imaging).

Visual illustrations

On D0 before application of the product, on D7, D14 and D28 after application, standardized pictures were taken of the full face with VISIA® CAS system (Canfield Imaging). The control of the repositioning took place directly on data-processing screen using overlay visualization of the images at various times of acquisition.

Subjective evaluation questionnaire

A subjective evaluation questionnaire, prepared by the clinical trial center and submitted to the Sponsor, was filled in by the subjects after use on D7, D14 and D28 to subjectively evaluate the global efficacy of the studied product and its appreciation.



