EFFICACY EVALUATION OF

SPIDER VEINS CREAM

ON BROKEN CAPILLARIES

Clinical evaluation

Sponsor
SWISSFORCE PHARMA AG
Blegistrasse 1
6343 Rotkreuz
SWITZERLAND

Investigator
DERMSCAN
114 Bd du 11 novembre 1918
69100 Villeurbanne
FRANCE

Investigator
CODIF
B.P. 11709 - 35417
St Malo Cedex
FRANCE

OBJECTIVES (16E3558)

To evaluate, on subjects presenting visible veins/thread veins and redness linked to couperose (telangiectasia), the efficacy of couperose thread and spider veins after 7, 14 and 28 days of twice-daily use:

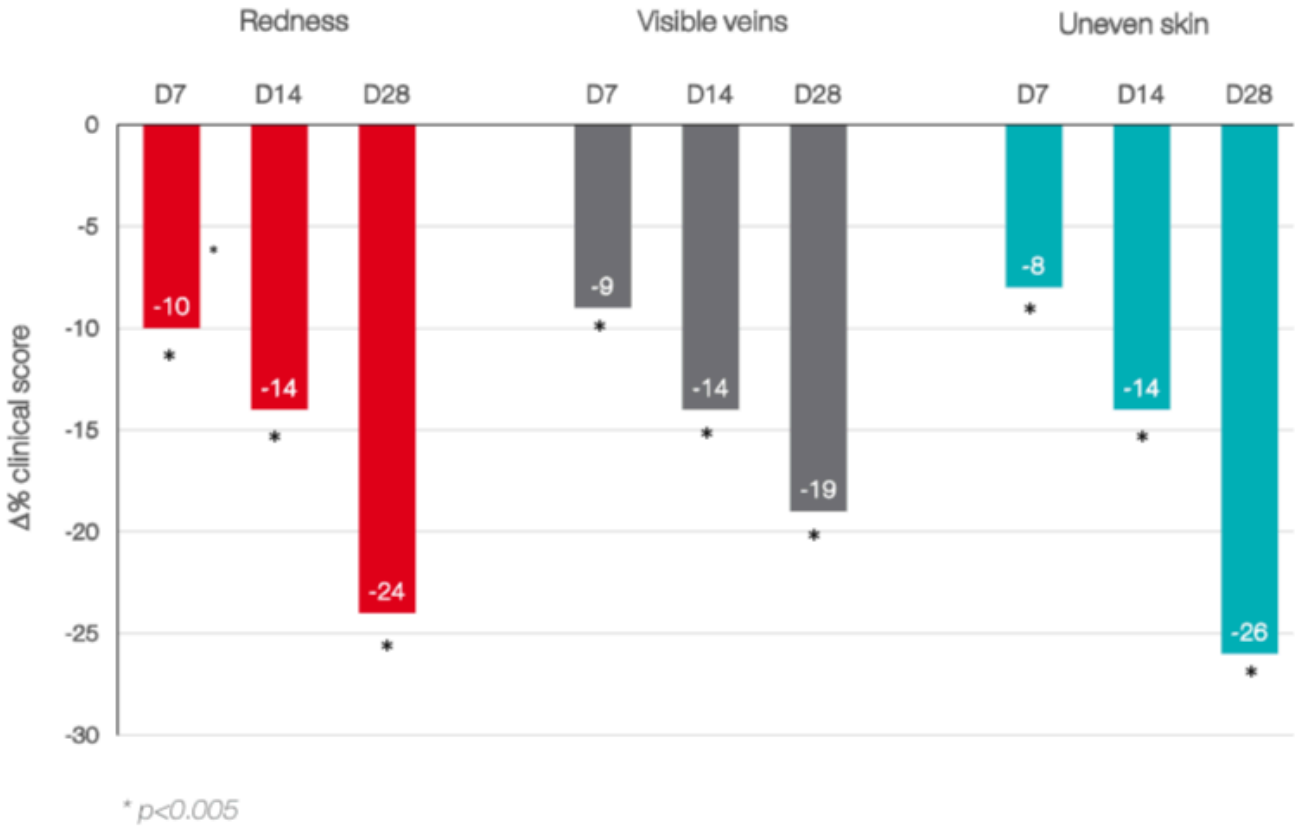
- **skin appearance**: evaluation of visible veins and skin redness by clinical score
- **cutaneous microcirculation**: evaluation of red blood cell concentration using TiVi® 600.
- **visual illustrations**: macrophotographs of the skin with VISIA® CAS system.
- **perceived efficacy and global appreciation**: subjects completed a subjective evaluation questionnaire

RESULTS

Skin appearance

Already from 7 days-of use, product presents a **significant efficacy**: skin is less red, veins are less visible and skin is more unified ($p<0.005$).

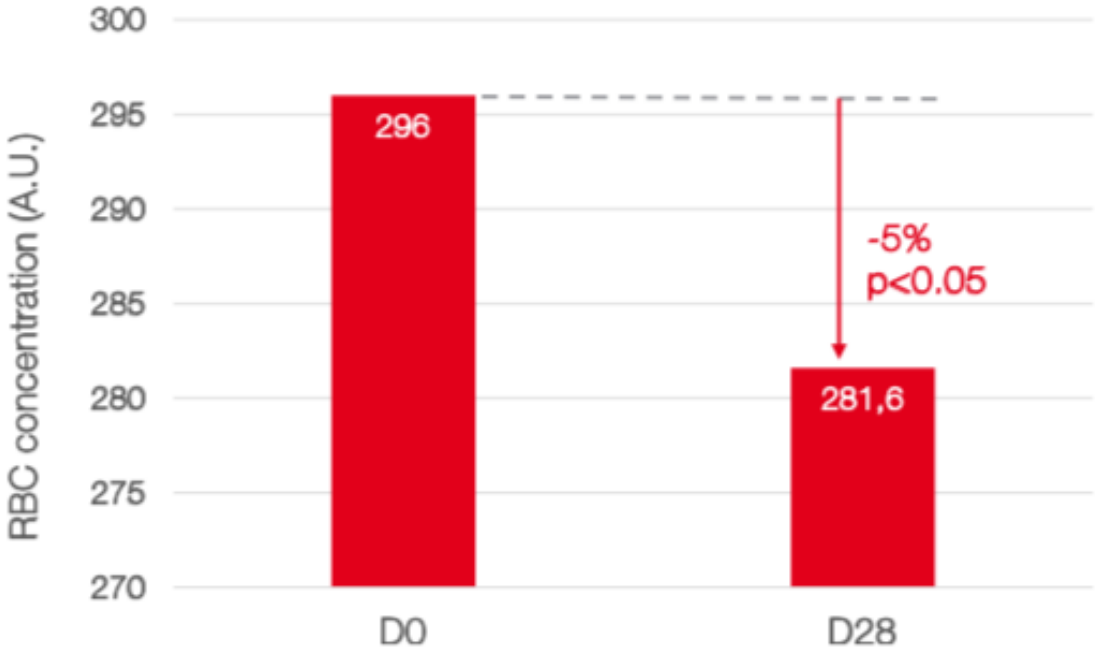
After 28 days of application, these beneficial effects are observed on more than 80% of the panel.



* $p<0.005$

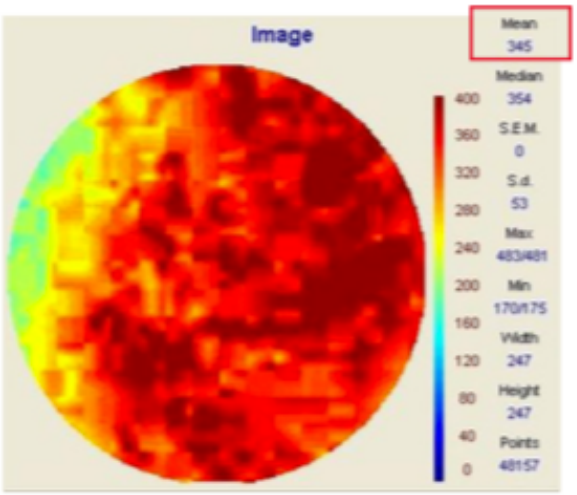
Cutaneous microcirculation

After 28 days of use, product presents **a significant vasoconstriction effect**: mean Red Blood Cell (RBC) concentration signifi cantly decreases on the skin (-5% in average; p=0.0039). 77% of the subjects presents a positive effect.

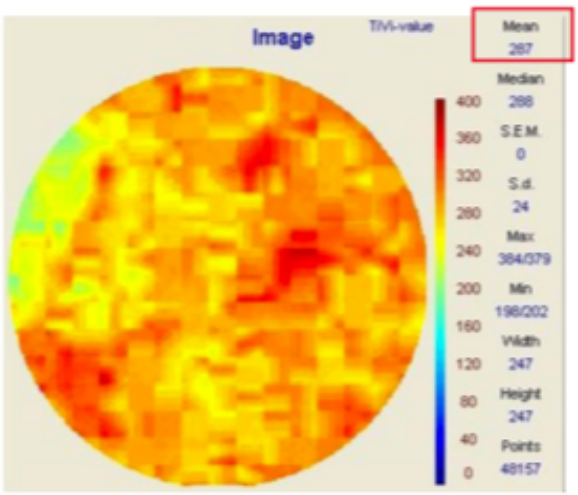


Examples of analysis obtained with TiVi on subject n° 13: mean RBC concentration went from 345A.U on D0 to 287A.U after 28 days.

D0



D28



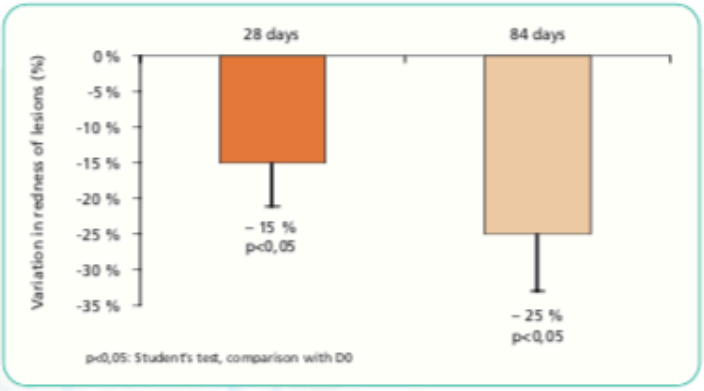
COFID 18E1641

Clinical test

Effect on spider veins

17 women between 35 and 65 years old (average age 49 years) applied twice a day for 84 days a cream containing **DERMOCHLORELLA D / DP** at 1%.
The volunteers had apparent lesions related to a bad venous function with heavy leg sensation: small varicose veins, small stellar angiomas, varicosities, petechia.
The effect of the product on spider veins was evaluated after 28 and 84 days of application.

- **DERMOCHLORELLA D / DP** at 1% visibly decreases the redness of the vascular lesions:
  - **-15%** on average and up to **-64%** after 28 days of use,
  - **-25%** on average and up to **-77%** after 84 days of use.
- Effect observed in **75%** of volunteers at the end of the test.



For the beauty of your legs, decrease vascular imperfections with:
DERMOCHLORELLA D/DP

RESULTS

Under the conditions of this study conducted under dermatological control, the product:

"SPIDER VEINS CREAM 100ML SWISSFORCE PHARMA

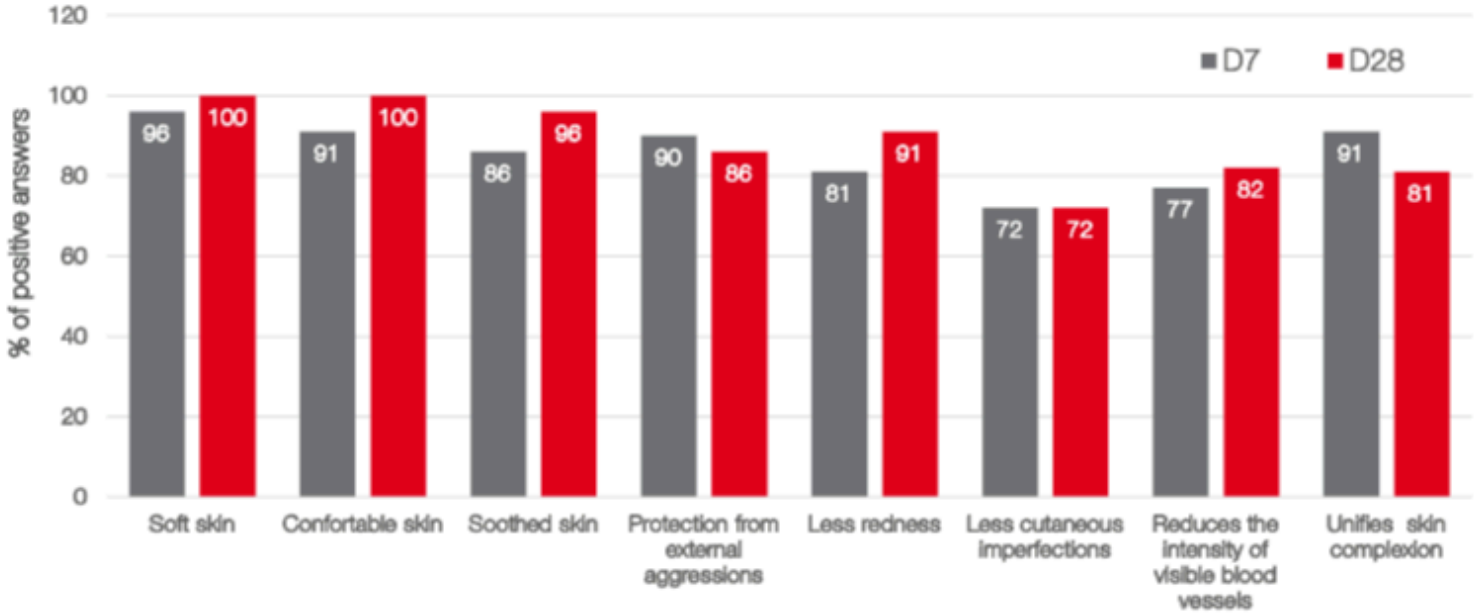
Ref.1901-01"

- is very well-tolerated on stripped skin.

Perceived efficacy and global appreciation

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

Perceived efficacy of product



Already after 7 days, 81% of the subjects see a reduction in skin redness and 77% observe a reduction in the intensity of visible blood vessels.

After 28 days of use, 100% of the subjects appreciate product and find it pleasant to apply.

95% of the subject would like to continue to use the product and 91% would like to buy it.

CONCLUSION

Already from 7 days of use, product presents a significant clinical efficacy: skin is less red, veins are less visible and skin is more unified. Furthermore, 81% of the subjects see a reduction in skin redness and 77% observe a reduction in the intensity of visible blood vessels.

After 28 days of twice daily use on the skin, product demonstrates a global efficacy:

- skin appearance is significantly improved (skin is less red, veins are less visible and skin is more even)
- cutaneous microcirculation significantly decreases
- a large majority of the panel is satisfied with the balm and 100% appreciate it. They find it efficacious on redness and blood vessels.

STUDY PROTOCOL

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

PANEL

The study was conducted on 22 healthy women, aged between 39 and 67 (average age: 54±2 years) and presenting visible veins/thread veins and redness linked to couperose (telangiectasia) on the skin.

APPLICATION METHOD

At home: the subjects applied the product twice-daily under normal conditions of use on the skin.

MEASUREMENT PRINCIPLE

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: redness from 0 (no redness) to 10 (visible redness); veins from 0 (no visible veins) to 10 (visible veins); skin aspect from 0 (unified skin) to 10 (uneven skin).

Cutaneous microcirculation

On D0 before application of the product and D28 after application, measurements of the red blood cell concentration on skin were performed with the Tissue Viability system TiVi® 600. This imaging system can “see through” the top layer of the skin and probe the dermal layer for information about the amount of Red Blood Cells (RBC) in the microvasculature. Measurements are stated in arbitrary units (A.U.).

Visual illustrations

On D0 before application of the product, on D7, D14 and D28 after application, standardized pictures were taken of the skin 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 at D7, D14 and D28 to subjectively evaluate the global efficacy of the studied product and its appreciation.