Study 16E3558

# EFFICACY EVALUATION OF COUPEROSE BALM ON ROSACEA

Clinical evaluation

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Sponsor

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## OBJECTIVES

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

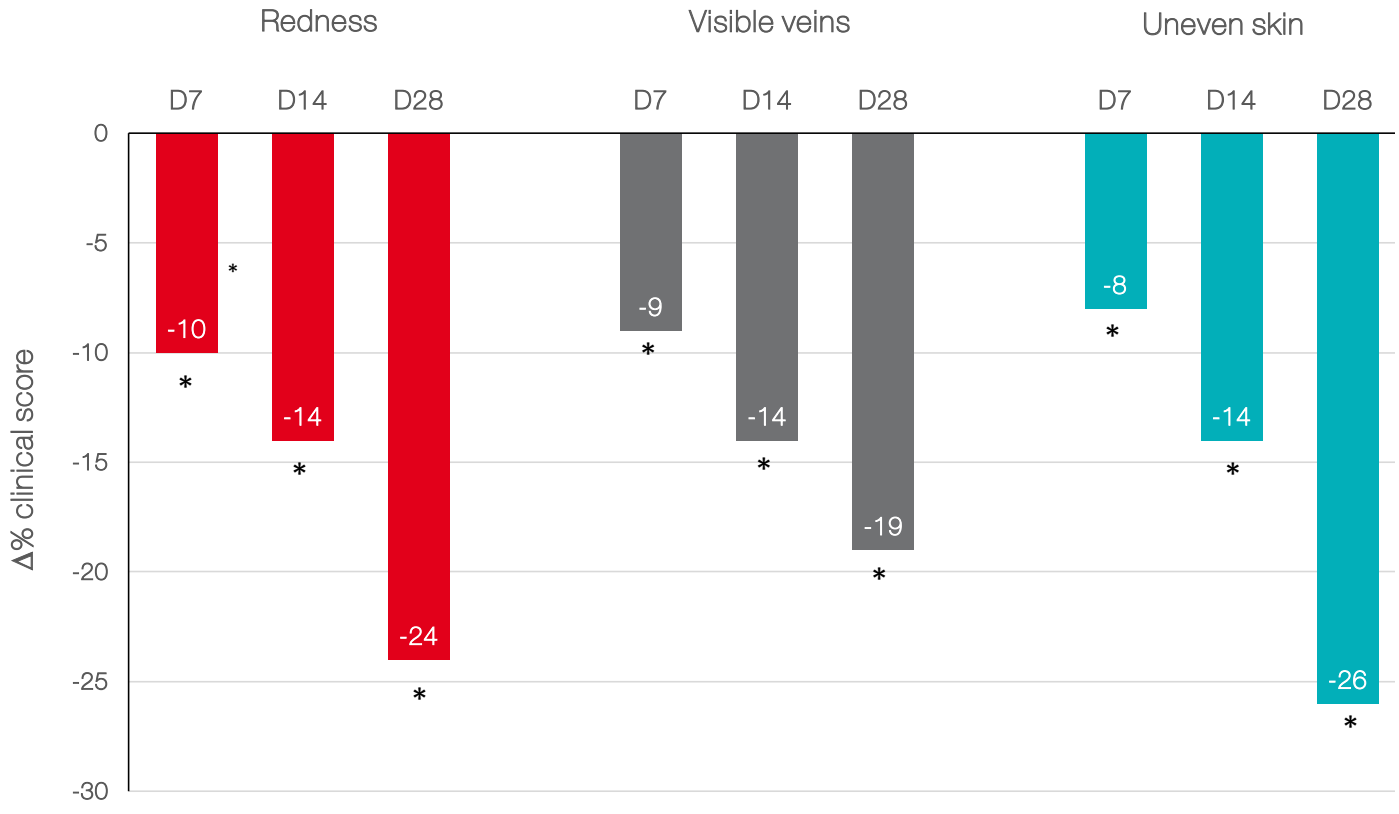
- **skin appearance**: evaluation of visible veins and skin redness by clinical score
- **cutaneous microcirculation**: evaluation of red blood cell concentration using TiVi® 600.
- **visual illustrations**: macrophotographs of the face with VISIA® CAS system.
- **perceived efficacy and global appreciation**: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

## RESULTS

### Skin appearance

**Already from 7 days of use**, product Couperose balm 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*

## Visual illustrations

**Examples of photographs** obtained with Couperose balm on subject n° 13. The skin becomes less red, veins are less visible and the skin is more unified.

| | **Normal light** *(color + shine)* | ***Cross-polarized light*** *(color only)* | **Cross-polarized light & RBX filter** *(red color only)* |
|---|---|---|---|
| *D0* |  |  |  |
| *D7* |  |  |  |
| *D28* |  |  |  |

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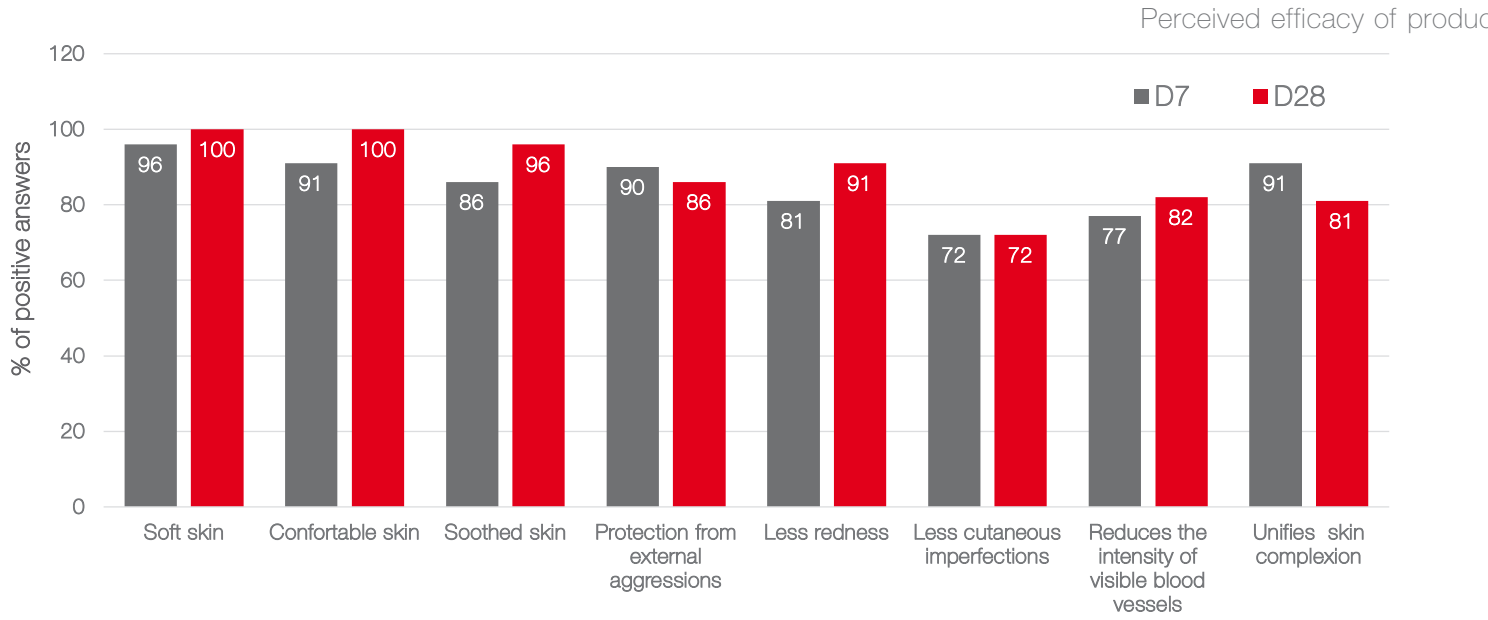
## Perceived efficacy and global appreciation

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

***Perceived efficacy of product «Couperose balm»***




**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** Couperose balm and find it pleasant to apply.

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

## CONCLUSION

Already from 7 days of use, product Couperose balm 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 face, Couperose balm 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.

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# 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 face.

## *APPLICATION METHOD*

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

## *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 face 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 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 at D7, D14 and D28 to subjectively evaluate the global efficacy of the studied product and its appreciation.


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