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Beauty Creations

*The Passion for Beauty*

# Pilisoft™ LS9760

Botanical hair-growth inhibitor

Longer lasting smoothness especially for sensitive skin

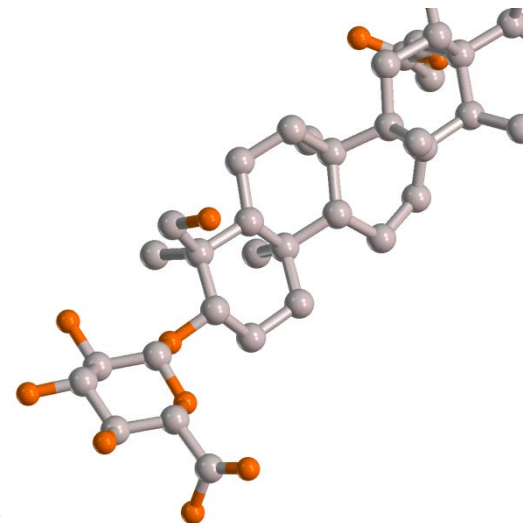


# Main active fraction identified, from *Gymnema sylvestre* leaves

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- ✂ Significant inhibition of hair follicle activity,
- ✂ Slowing down of hair growth,
  - Allows reducing the frequency of hair removal treatments
- ✂ Reduction of hairiness.
  - Improved aesthetics & easier shaving

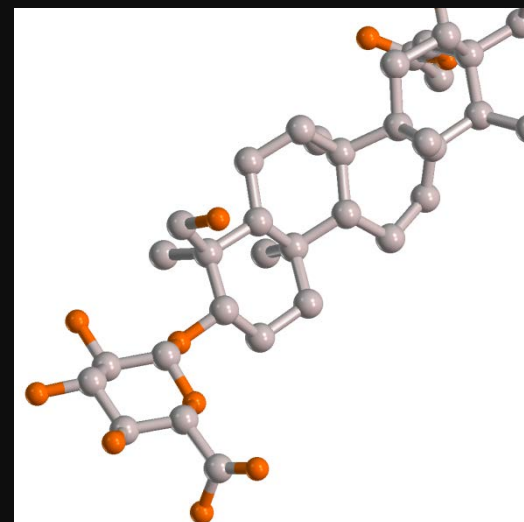


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- PILISOFT BENEFITS
- VEGETAL ORIGIN
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## Solution to decrease hair growth and maintain skin softness (as if just shaved/depilated)

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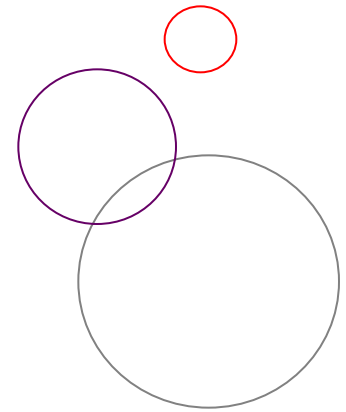
Botanical extract – identified tracer,

Significant clinical effect after only one month of use,

Suitable for sensitive skin : face and body care,

Preservative free,

Opportunity for depilatory/body care market following the trend for more premium products with added benefit.

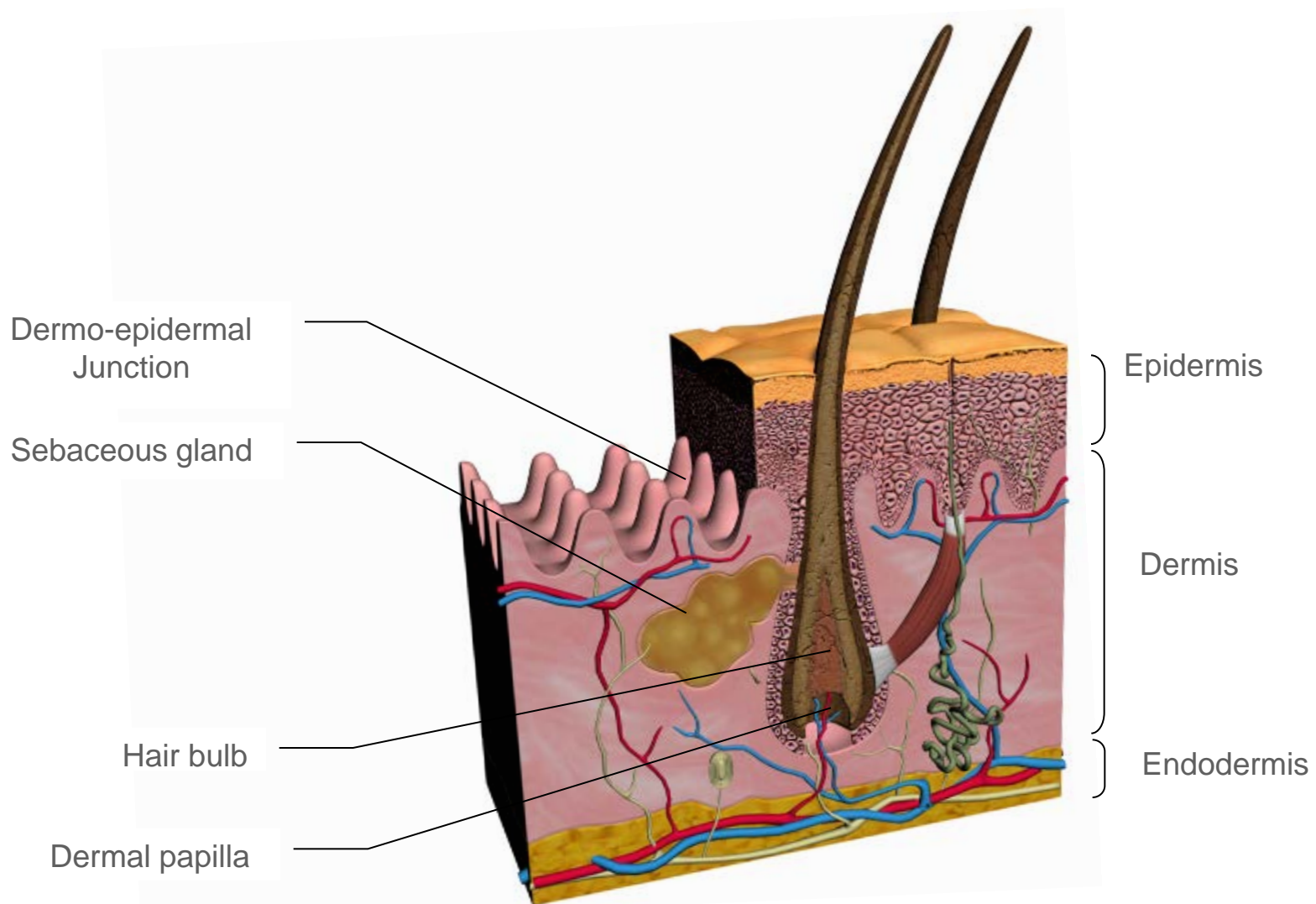




# In brief

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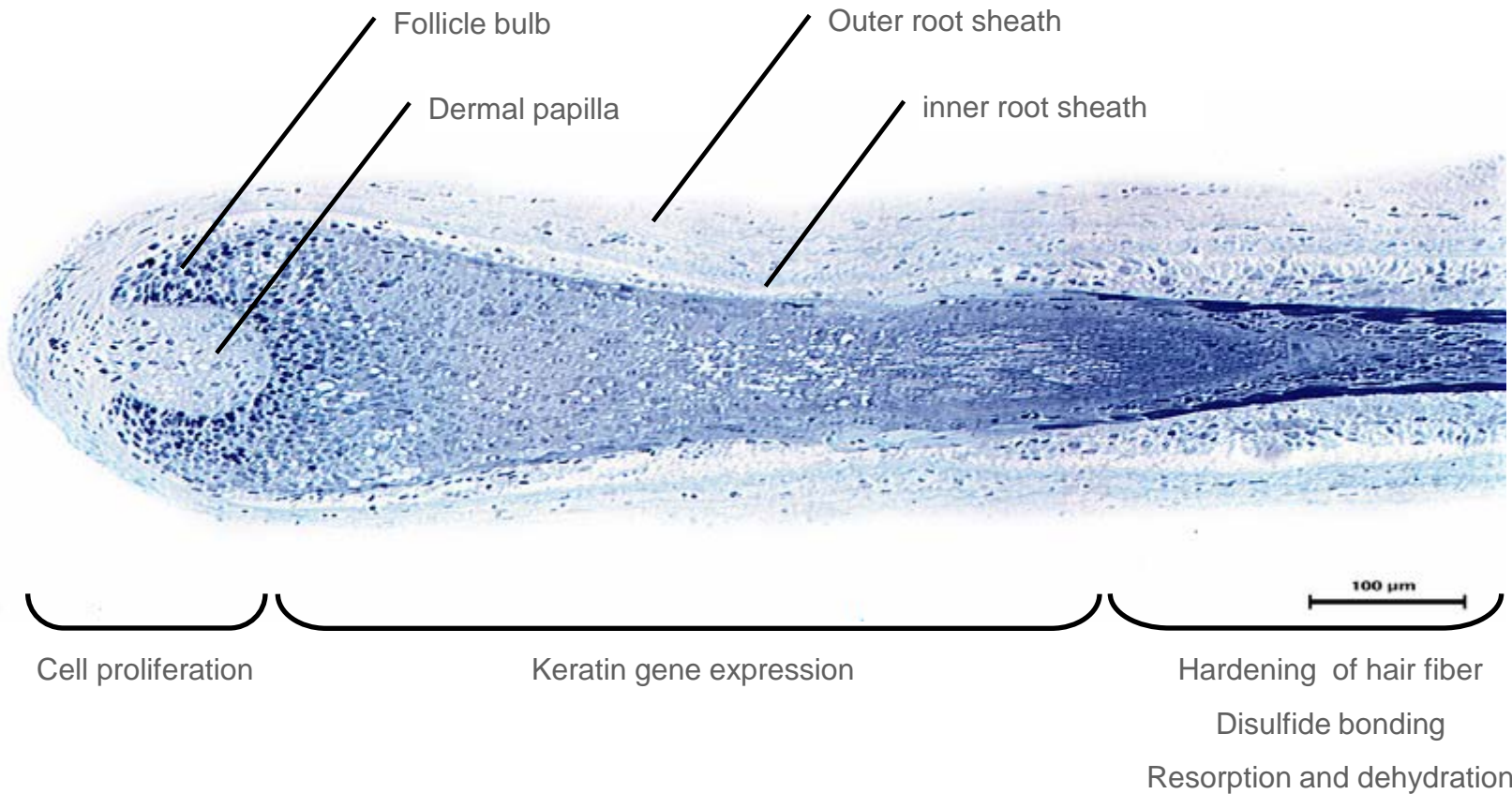
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# Pilisoft™ targeted effect on hair follicles

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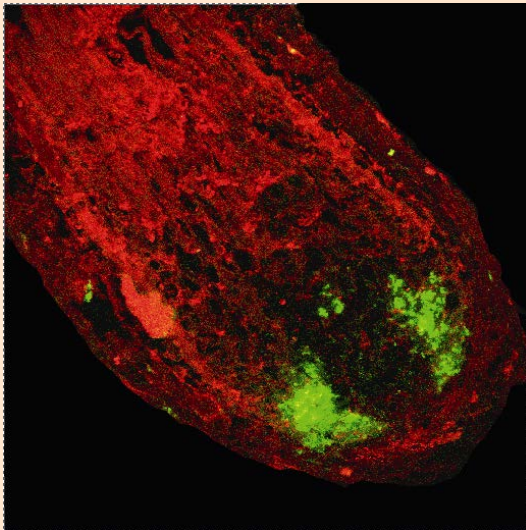


# Hair follicle activity inhibitor

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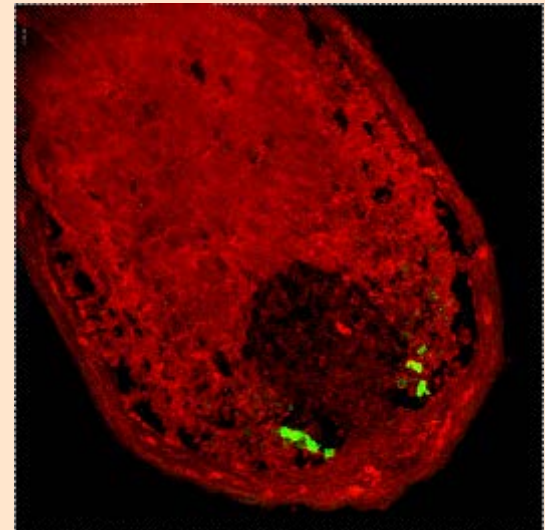
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- ✗ Evaluation of PILISOFT™ ability to inhibit hair growth *in vitro* using Philpott's model of hair follicles in culture.



Hair follicle after 3 days of culture in Williams E medium.

Illustration of anti-mitotic activity of *Gymnema sylvestre* Leaf Extract on hair follicle sections (Ki67).



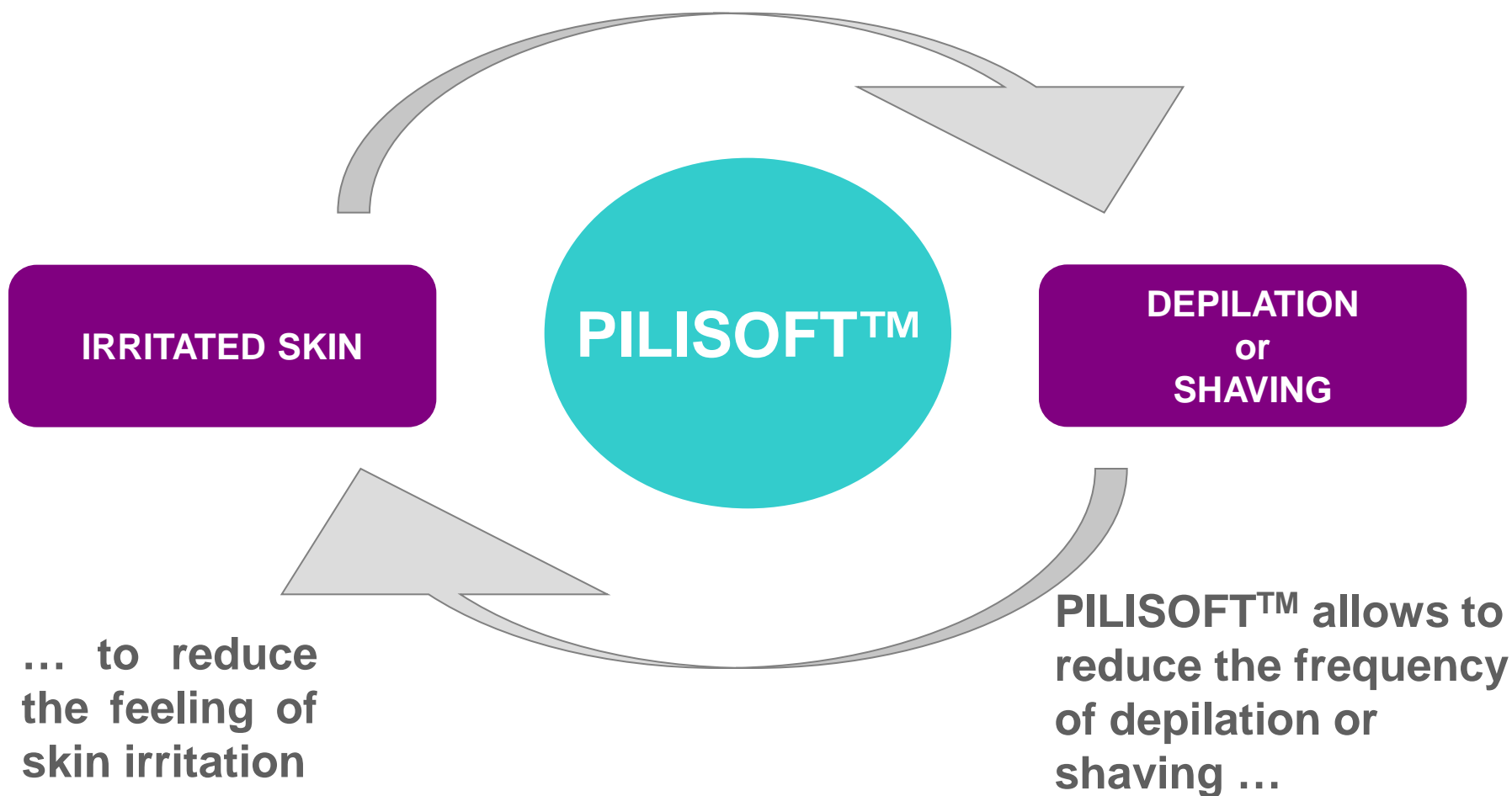
Hair follicle after 3 days of culture in William E medium with 0.025% of *Gymnema sylvestre* (0.5% of PILISOFT™).

- ✗ PILISOFT™ has significantly inhibited the hair growth of hair follicles in culture

# Repeated depilation or shaving can be harsh on sensitive skin

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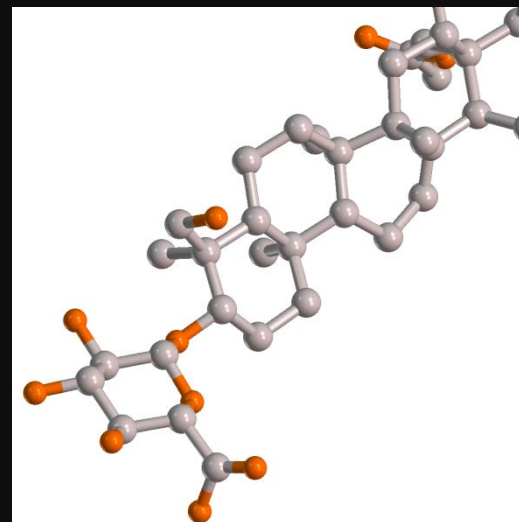


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- EFFICACY TESTS



# Vegetal origin

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## ✂ *Gymnema sylvestre* leaf extract



Native plant of the  
Indian Deccan Plateau.  
Indian Nature Sanctuary

From a dry forest  
older than the  
Himalaya mountain  
range.



✂ *Gymnema sylvestre*, a woody climber covering the tops of trees. Belongs to the Asclepiadaceae family.

## *Gymnema sylvestre* traditional uses

- ✂ Used since 2500 years in Ayurvedic (traditional Indian) medicine
- ✂ Chewing leaves reduces the taste of sugar in the mouth (to fight sugar cravings)
- ✂ Root is used as cough medicine and as remedy for snake bite.

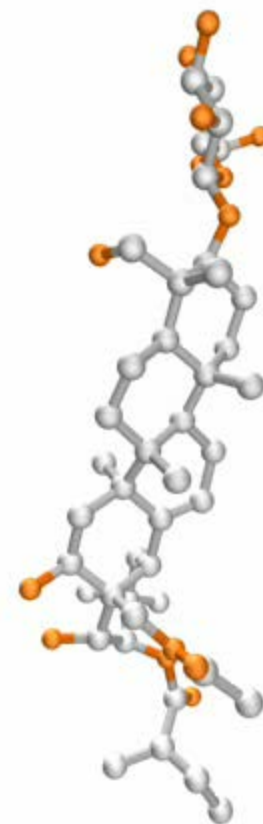
# Vegetal origin

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## *Gymnema sylvestre* leaves extract

- ✗ PILISOFT™ is extracted from *Gymnema sylvestre* leaves,
- ✗ Main active fraction is gymnemic acids, triterpenoid saponins belonging to the oleanane class.



Gymnemic acid I

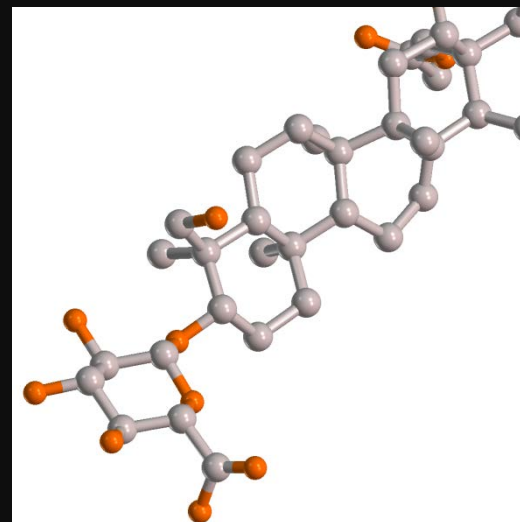


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# Cytotoxicity on human fibroblasts (MRC5)

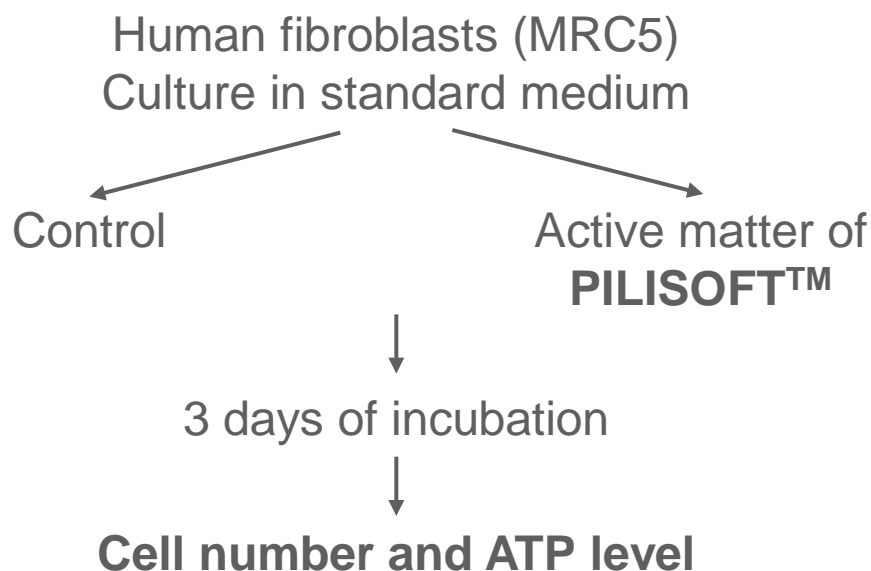
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## Purpose

Evaluation of the cytotoxicity of the active matter of PILISOFT™ to confirm that the anti-proliferative activity is not linked to toxicity.

## Protocol

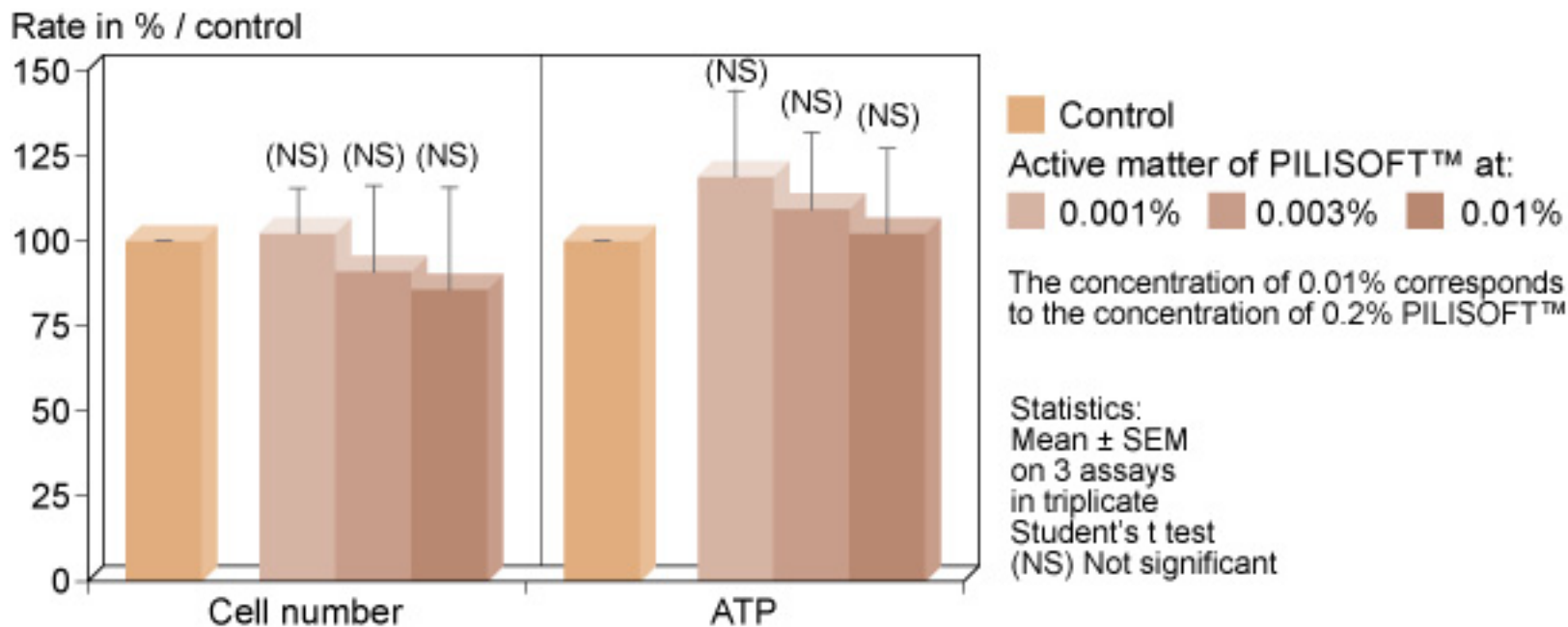


# Cytotoxicity on human fibroblasts (MRC5)

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## Results with active matter of PILISOFT™



# Cytotoxicity on human fibroblasts (MRC5)

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## CONCLUSION:

No toxicity on MRC5 for the active matter of PILISOFT™ in a dose range similar to the concentrations used for testing the anti-proliferative activity.



# Anti-proliferative activity on human keratinocytes

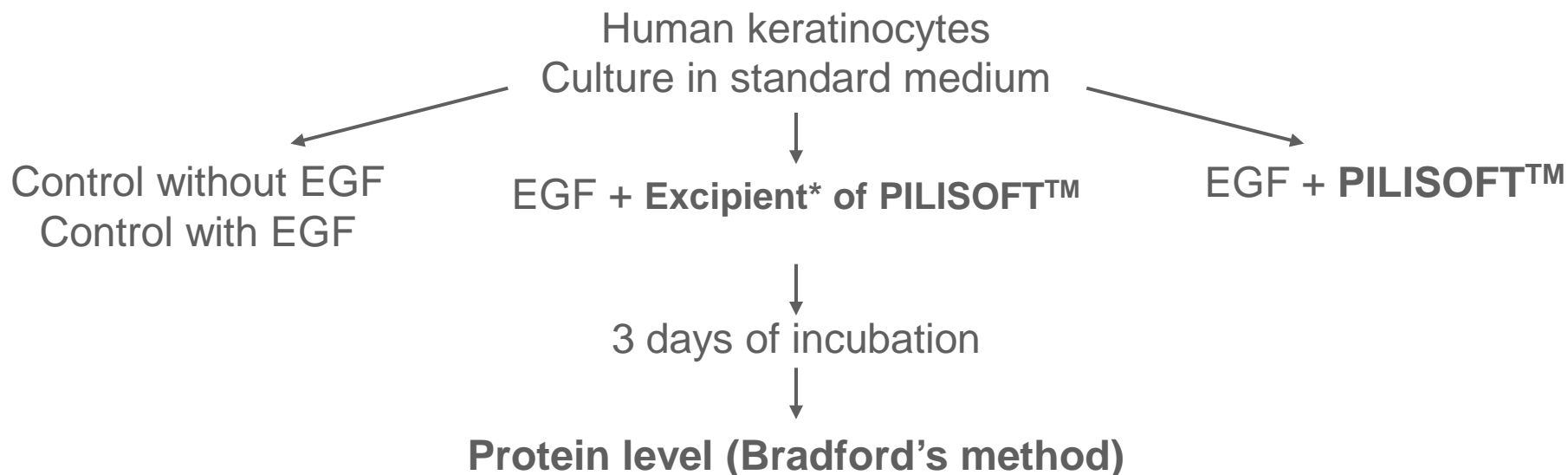
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## Purpose

Evaluation of the potential of the active to inhibit hair growth through **reduction of the proliferation of epidermal cells.**

## Protocol



EGF = Epidermal Growth Factor

\*Excipient of PILISOFT™ = Pentylene Glycol/Water

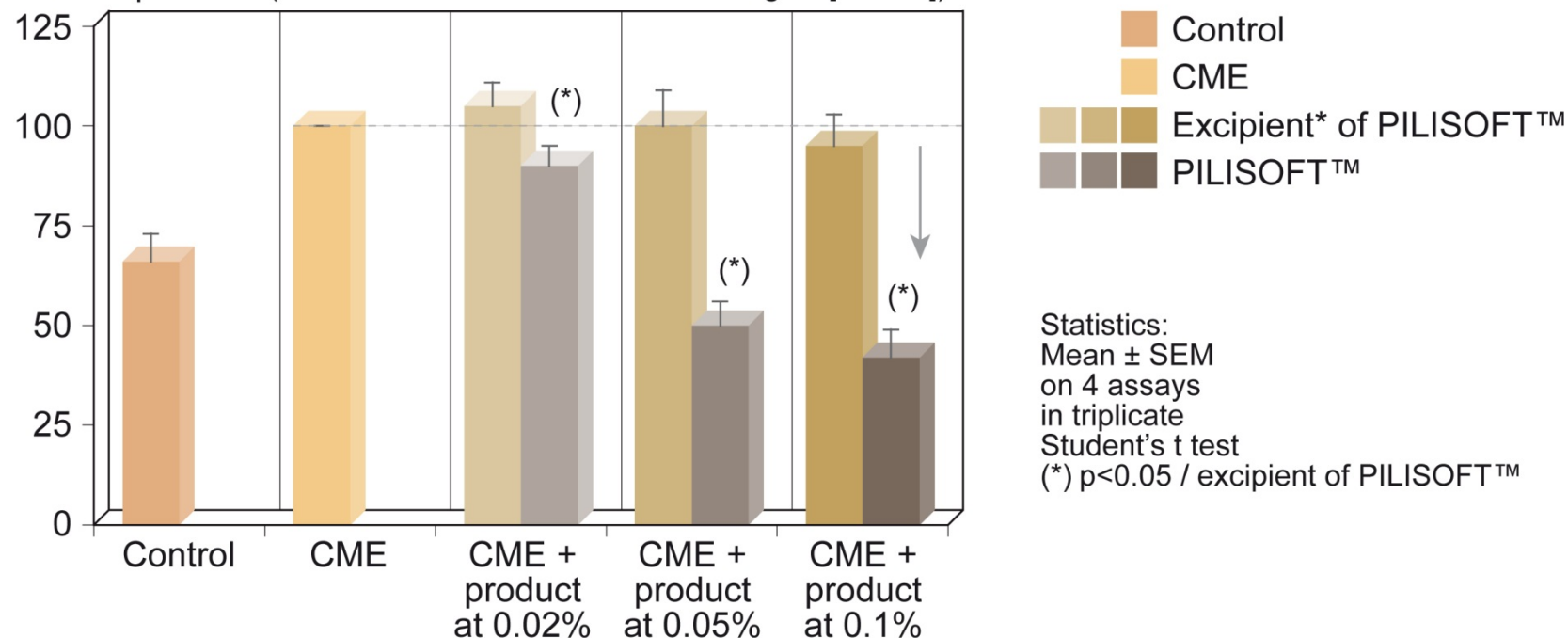
# Anti-proliferative activity on human keratinocytes

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## Results with PILISOFT™

Rate of proteins (% / control medium with EGF at 10 ng/ml [= CME])



\* CME = Control Medium with EGF at 10 ng/ml

\*Excipient of PILISOFT™ = Pentylene Glycol/Water

# Anti-proliferative activity on human keratinocytes

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## CONCLUSION:

**PILISOFT™** has significantly reduced, in a dose dependant way, the proliferation of human keratinocytes stimulated by EGF.

The excipient used for PILISOFT™ was confirmed to have no significant effect at comparable concentration.

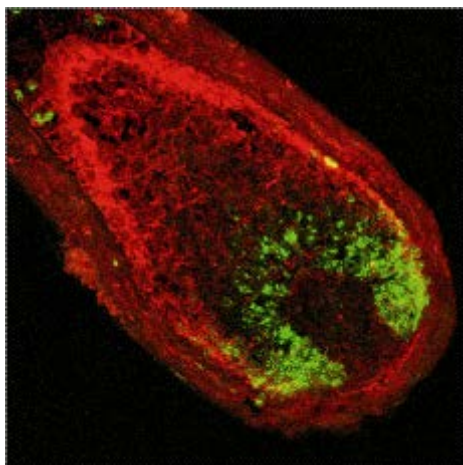
# Anti-mitotic effect of Pilisoft™: *in vitro* test

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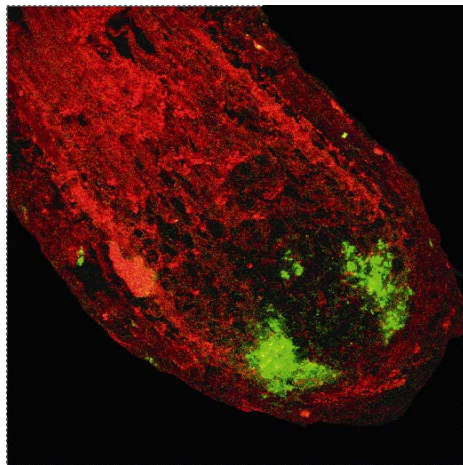
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## Illustration *Gymnema sylvestre* Leaf Extract activity on hair follicles.

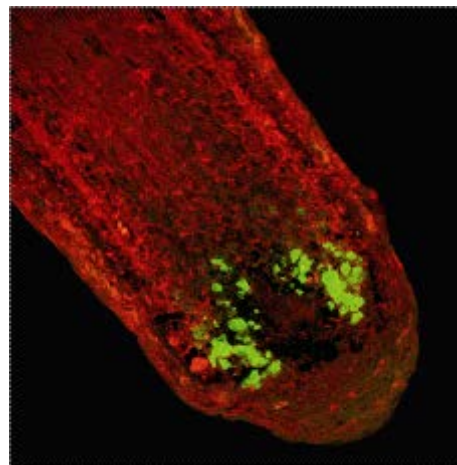
Ki67\* expression on isolated sectioned human hair follicles.



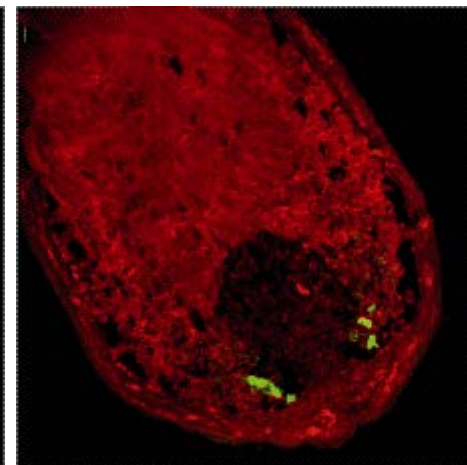
Control hair follicle at D0.



Control hair follicle after 3 days of culture in William E medium.



Hair follicle after 3 days of culture with 0.01% of *Gymnema sylvestre* leaf extract (0.2% PILISOFT™).



Hair follicle after 3 days of culture with 0.025% of *Gymnema sylvestre* leaf extract (0.5% PILISOFT™).

**The green staining is proportional to mitotic activity and clearly shows the reduction of mitotic activity.**

\*Ki67: immunostaining to the Ki67 antigen is a quick and efficient method for evaluating cells proliferation.



# Anti-hair follicle growth: *in vitro* test

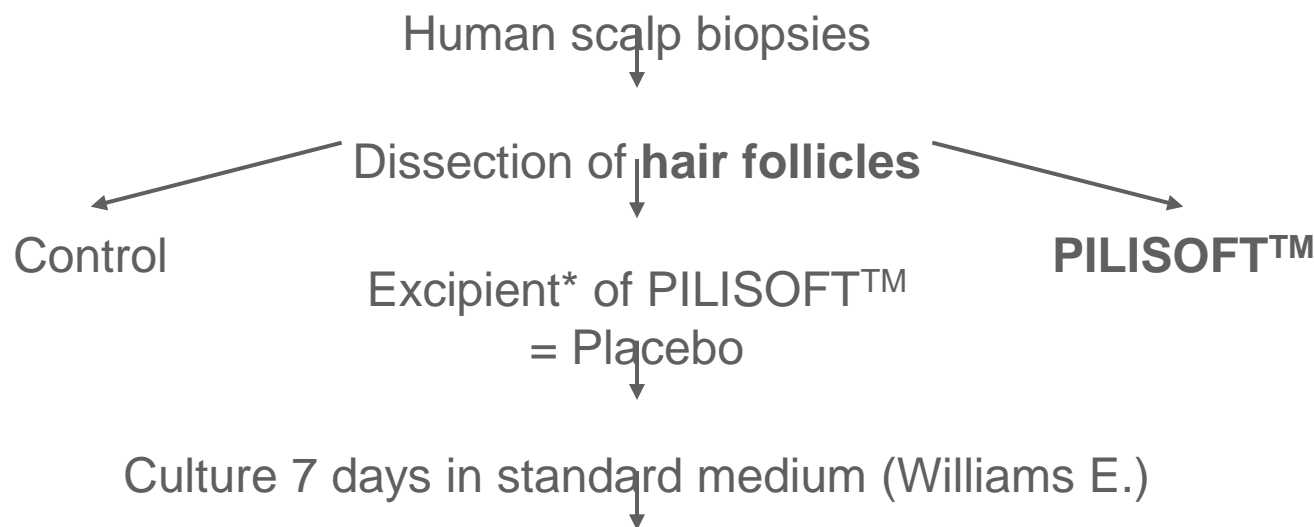
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## Purpose

**Direct evaluation** of the potential of PILISOFT™ to inhibit **hair growth** *in vitro* on the Philpott's model of hair follicles in culture.

## Protocol



**Evaluation of hair growth at 3 and 7 days by measuring of hair length**  
(image analysis)

\*Excipient of PILISOFT™ =Pentylene Glycol/Water

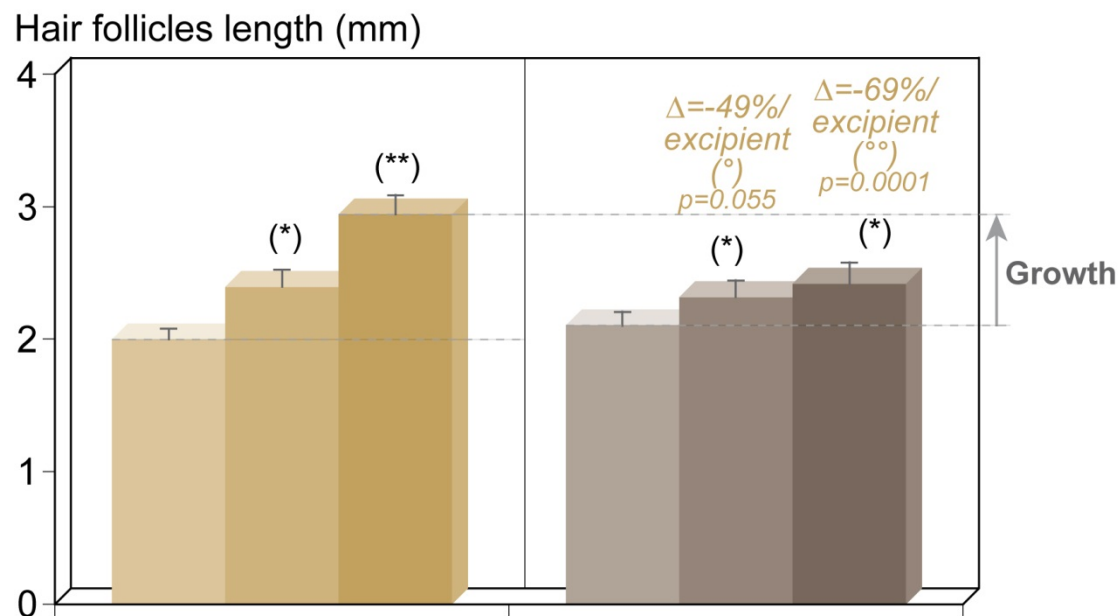
# Anti-hair follicle growth: *in vitro* test

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## Results with PILISOFT™

(Test done on hair follicles from 6 different donors, 10 follicles analyzed per donor and test condition).



Excipient\* of PILISOFT™ at:

■ D0 ■ D3 ■ D7

PILISOFT™ at 0.5% at:

■ D0 ■ D3 ■ D7

Statistics:

Mean ± SEM

on 6 assays

Paired T test

(\*) Significant / D0

(\*\*) Significant / D0 and D3

Not paired T test

(°) Close to significance / excipient

(°°) Significant / excipient

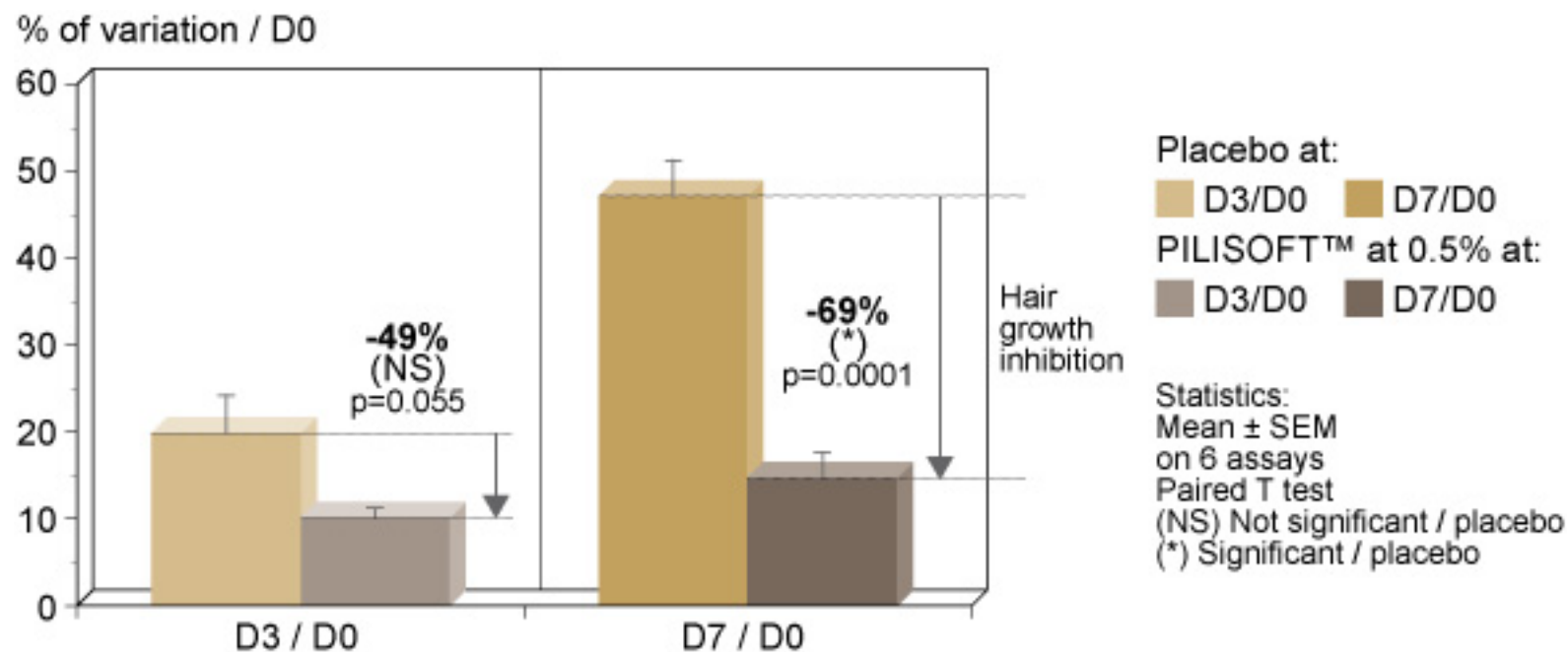
# Anti-hair follicle growth: *in vitro* test

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## Results with PILISOFT™ – Inhibition of hair growth

(Test done on hair follicles from 6 different donors, 10 follicles analyzed per donor and condition).

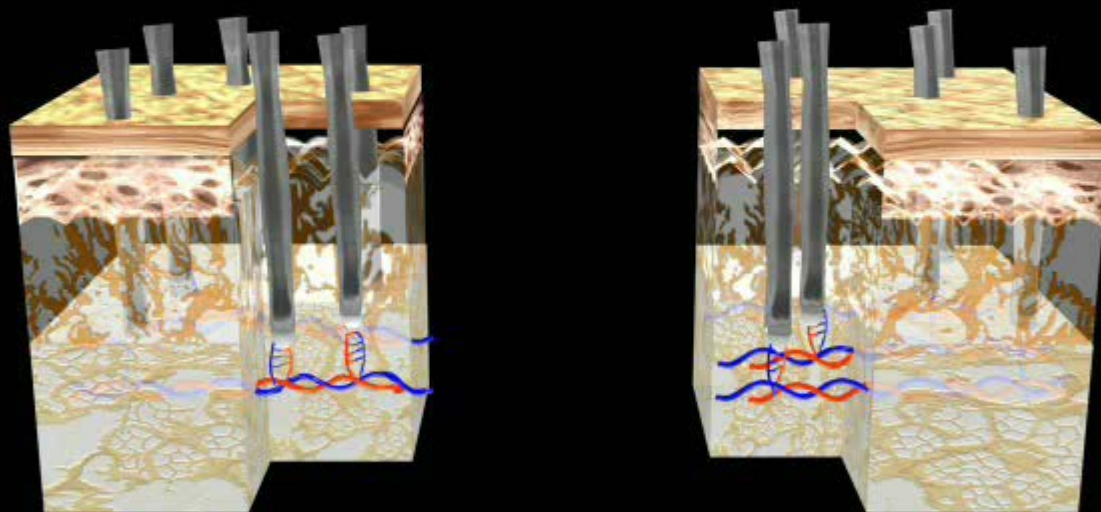


# Anti-hair follicle growth: *in vitro* test

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Simulation of hair follicles growth, based on *in vitro* test results.



Placebo

Day 0

PILISOFT™

Hair growth in presence of PILISOFT™ is slowed down.

# Anti-hair follicle growth: *in vitro* test

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## CONCLUSION:

**PILISOFT™** has significantly inhibited the hair follicle culture in comparison to placebo (=excipient used for PILISOFT™).

# Anti-hair follicle growth: *in vivo* test

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## Protocol

Placebo  
gel



Gel with  
1% PILISOFT™

### First Step

Shaving (1) of the both legs (D-7)



Image acquisition with Hirox videomicroscopy  
7 days after shaving (1)



### Second Step

28 days of treatment,

Randomized application of tested products



Shaving (2) of the both legs (D21)



Image acquisition with Hirox videomicroscopy  
7 days after shaving (2) (D28)

**Daily** application  
during 28 days of  
treatment

**D0**

Evaluation of hair  
growth **before**  
treatment

**D28**

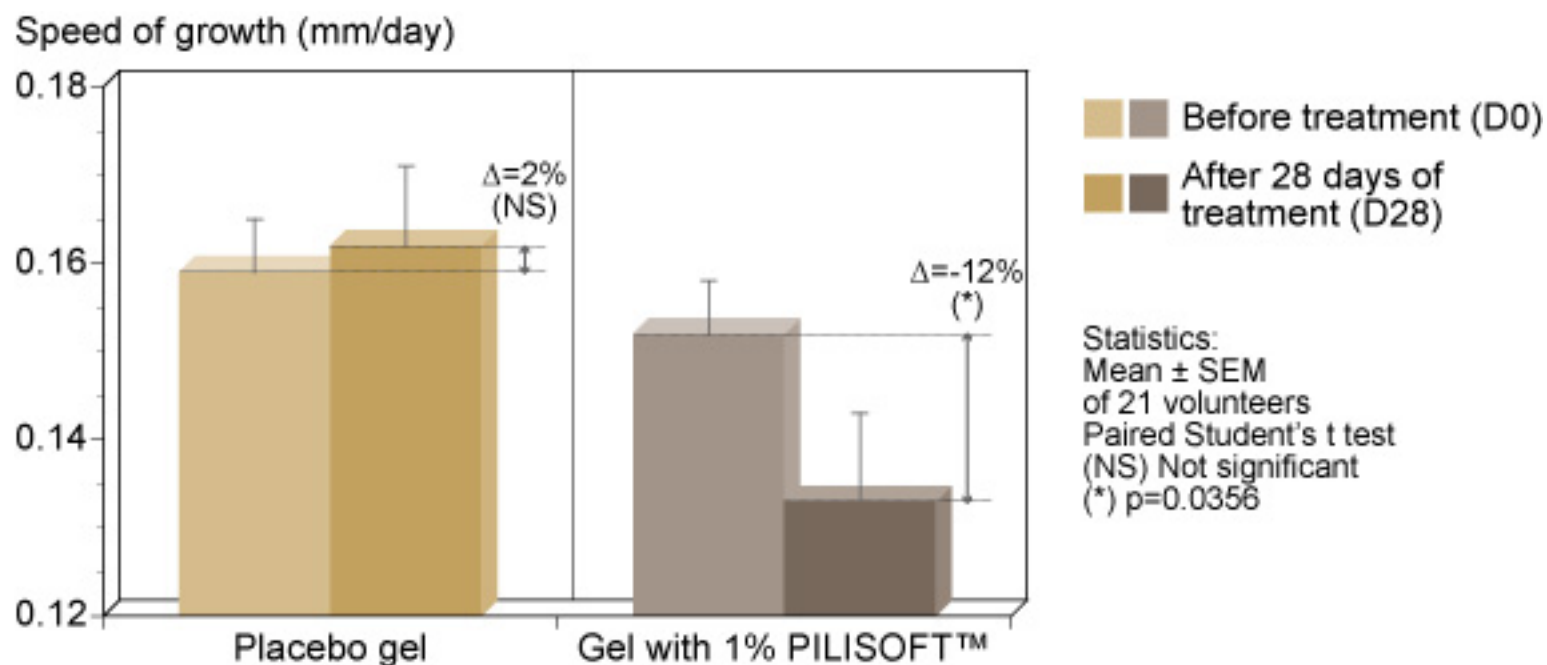
Evaluation of hair  
growth **after** treatment

# Anti-hair follicle growth: *in vivo* test

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## Results with PILISOFT™



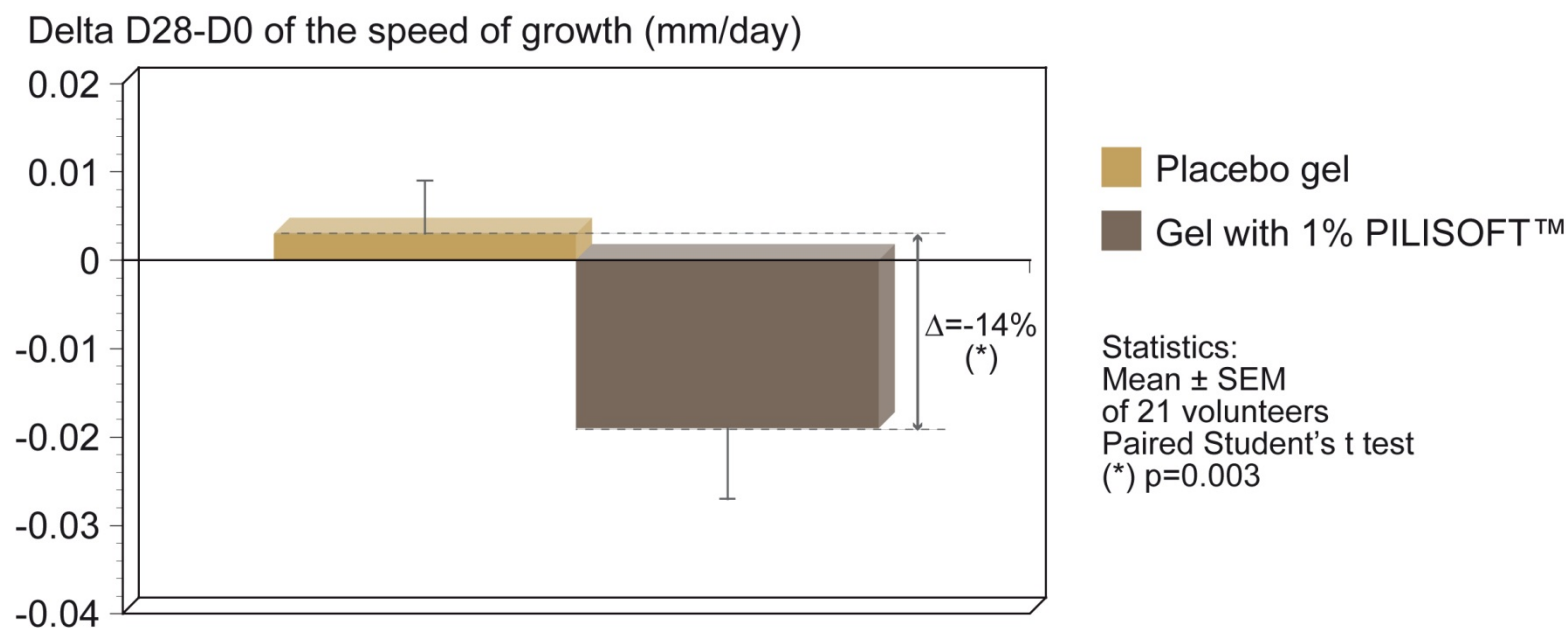


# Anti-hair follicle growth: *in vivo* test

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## Results with PILISOFT™



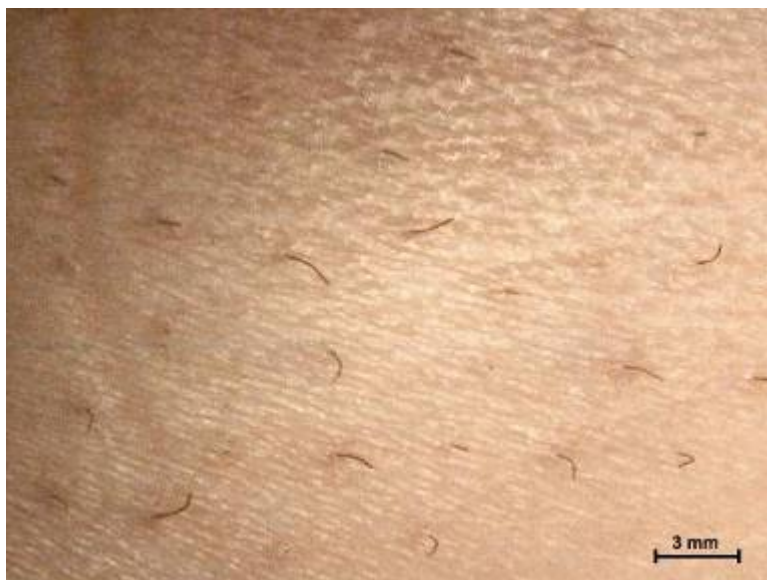
# Anti-hair follicle growth: *in vivo* test

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## Results with placebo

Illustration of anti-hair growth effect: placebo gel.



PLACEBO D0



PLACEBO D28

**No visible hair growth reduction with placebo**

# Anti-hair follicle growth: *in vivo* test

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## Results with PILISOFT™

Illustration of anti-hair growth effect: gel with 1% PILISOFT™.



PILISOFT™ D0



PILISOFT™ D28

**Visible hair growth reduction with PILISOFT™**

# Anti-hair follicle growth: *in vivo* test

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## CONCLUSION:

PILISOFT™ at 1% in a gel has **significant anti-hair growth** activity.

After 28 days of treatment, (the speed of) hair growth was **reduced by 12%** for the gel containing **1% PILISOFT™**, whereas the placebo gel did not modify the hair growth.

In addition, the **reduction of hair growth** can visibly be perceived after only 4 weeks of treatment.

# Status

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## Patent status

WO 2005/067953 A1 [EP (DE, ES, GB, IT, FR), JP, KR and US].

## Toxicity tests

Tests with Gymnema Extract PW LS 9825 (active matter of PILISOFT™)

- LLNA (10% weight dilution): not sensitizing,
- Ames test: not mutagenic.

Tests with PILISOFT™

- Het Cam (3% weight dilution): not irritant,
- primary dermal irritation (patch test, 1%): no dermal irritation potential.

# Technical data

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**INCI Name** : Water (and) Pentylene Glycol (and)  
Gymnema Sylvestre Leaf Extract

**Preservative** : preservative free

**Aspect** : opaque amber-colored liquid with a  
characteristic odor

**Dose of use** : 0.5 to 1%

**Solubility** : soluble in water, insoluble in oils

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# PILISOFT™ LS 9760

Botanical hair-growth inhibitor

Longer lasting smoothness especially  
for sensitive skin





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