

# Kouriles

THE RIGHT ANSWER TO THE MOST  
COMMON SYMPTOMS OF DERMATITIS

Focus on : SEBORRHEIC DERMATITIS

Although the exact cause of seborrheic dermatitis is not yet known, there is strong evidence showing that fungi such as *Pityrosporum ovale* and *Malassezia ovale* play an important role in this skin affection

These organisms are normally present on the skin, but when their number increases, skin problems occur

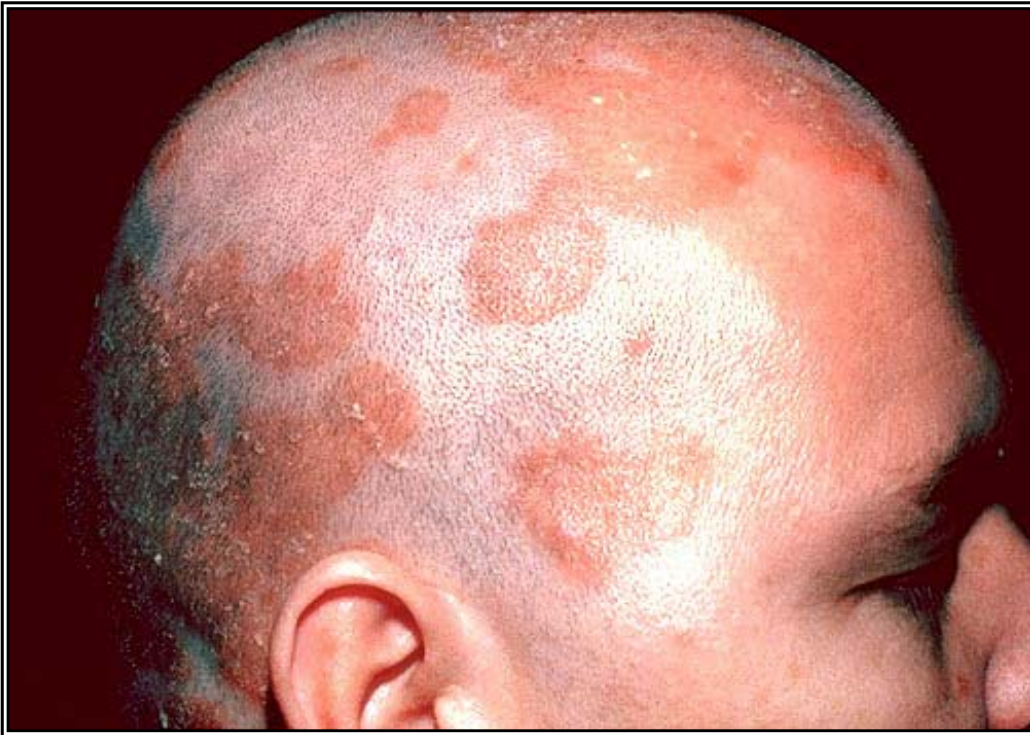
Fungi metabolize the skin's lipophilic barriers into short chain fatty acids.

Excessive fatty acids accumulation causes skin inflammation and therefore scaling, redness and itching

# KOURILES

## Emulsion and Shampoo

Focus on : SEBORRHEIC DERMATITIS

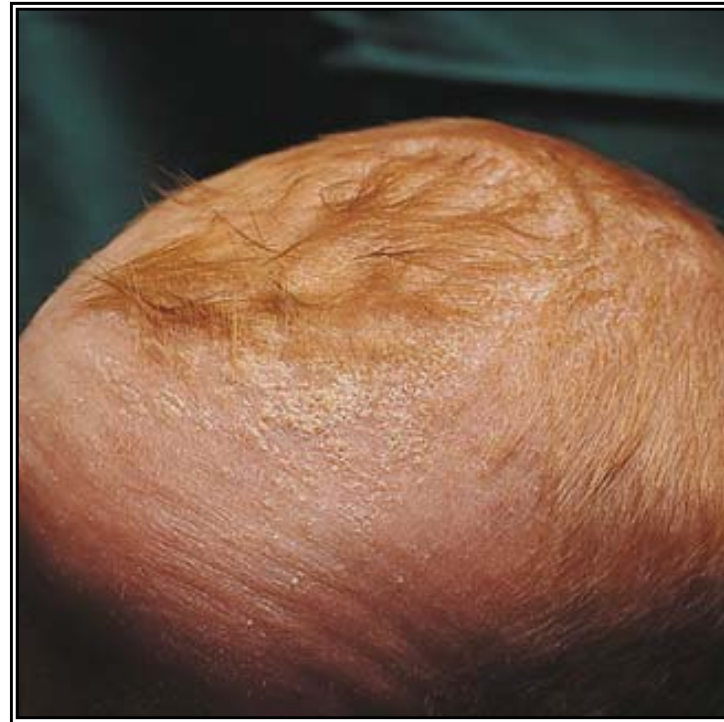


Seborrheic dermatitis affects several parts of the body such as the face and chest, the creases of the arms, legs and groin

# KOURILES

## Emulsion and Shampoo

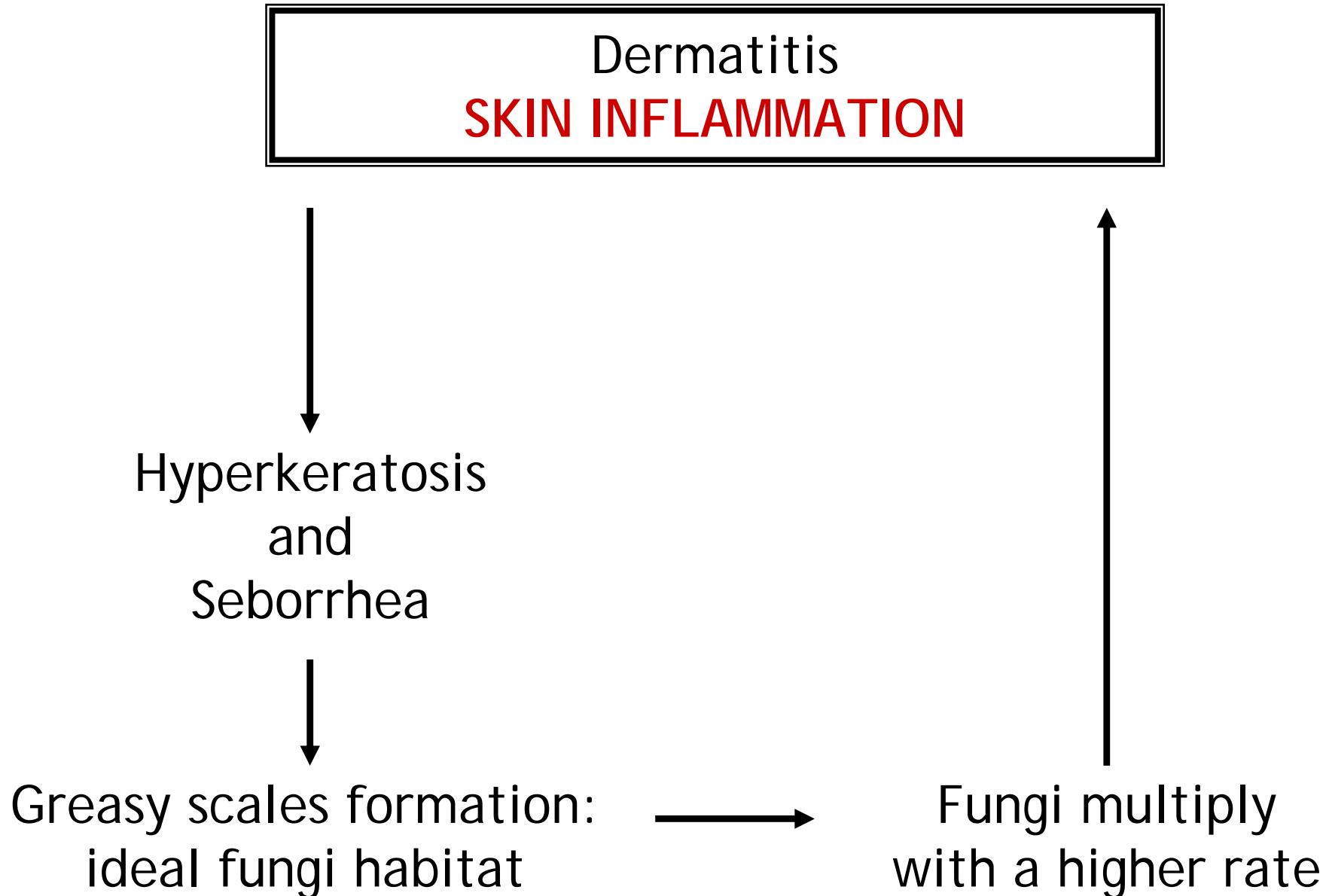
### Cradle Cap : INFANTILE SEBORRHEIC DERMATITIS



Cradle cap is very common in babies.  
It usually appears during the first couple of weeks of the infant's life.

# KOURILES

## Emulsion and Shampoo



# KOURILES

## Emulsion and Shampoo

HYPERKERATOSIS  
SEBORRHEA



SCALING

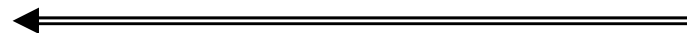


**SEBORRHEIC  
DERMATITIS**  
A vicious circle



FUNGI  
INFECTION

INFLAMMATION



### SEBORRHEIC DERMATITIS THERAPY

Pharmacological treatment options for seborrheic dermatitis include:

**antifungal preparations** (mainly azole agents) that decrease colonization by lipophilic yeasts

**anti-inflammatory agents** such as topical steroids

**sebosuppressive agents** such as isotretinoin, as a last resort in refractory disease

Cases of seborrheic dermatitis affecting the **scalp** can be treated with **antidandruff shampoos** containing selenium sulfide, pyrithione zinc or azole agents

### SEBORRHEIC DERMATITIS THERAPY

Anti-mycotic agents have a quick onset but since their use is often sensitizing (ketoconazole) it has to be discontinued

Steroids are highly potent but can cause severe adverse reactions like cutaneous atrophy, hypertrichosis and leucoderma among others

The efficacy of shampoos and other cosmeceuticals often lacks clinical evaluation.

Further more many of these products are only poorly tolerated



# KOURILES

## Emulsion and Shampoo



*The ideal treatment*

FIGHT FUNGAL INFECTION

REDUCE INFLAMMATION

INHIBIT SEBORRHEA

HALT SCALING

CLINICALLY PROVEN

PERFECTLY TOLERATED

## Emulsion

A specifically formulated lotion that fights mycotic and bacterial infections, soothes, hydrates and relieves itching skin

## Shampoo

A well tolerated antimycotic active principle and an anti-sebum agent combined with a particularly gentle cleansing base

# KOURILES

## Emulsion and Shampoo

### KOURILES Emulsion

#### ACTIVE PRINCIPLES

#### ACTION

Octopirox



Anti-mycotic

Sebomine



H.U.C.P



Dermal protection

Norgel



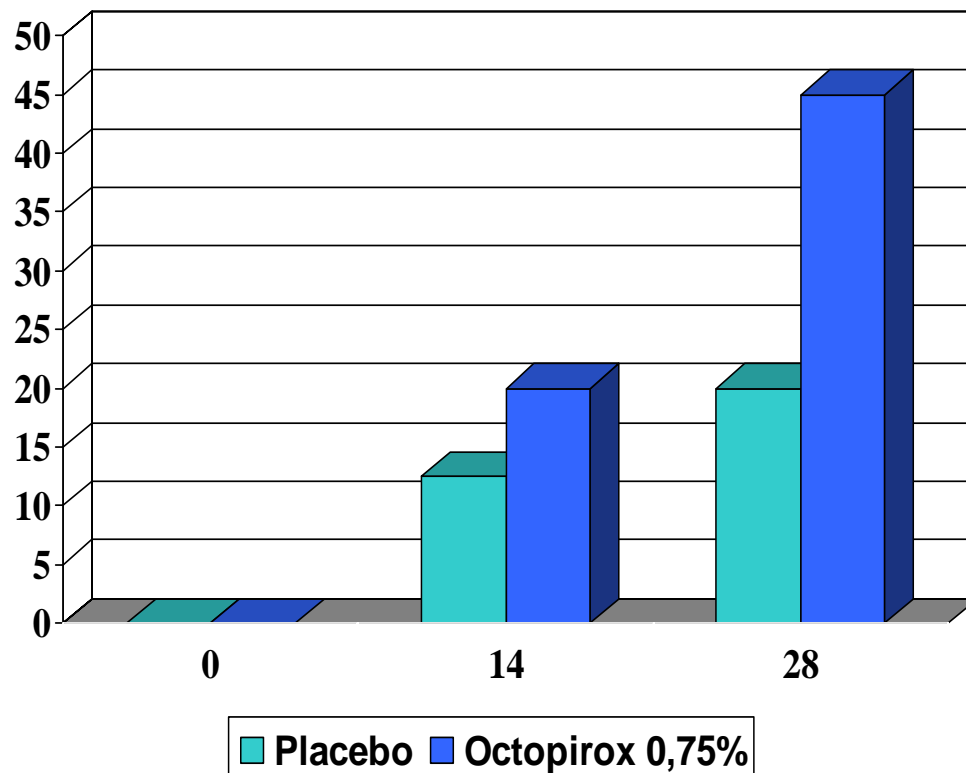
Deep hydration

# KOURILES

## Emulsion and Shampoo

Octopirox

PIROCTONE OLAMINE (Octopirox) has anti-bacterial, anti-mycotic, anti-dandruff and anti-oxidant properties



Significant decrease of dandruff in a 28 days treatment with a lotion of 0.75 % of Octopirox vs placebo

### Sebomine

SEBOMINE (SB 12) is a mixture of 4 substances normally present in human skin. Sebomine has strong anti-mycotic and anti-bacterial activity by interfering with fungal and bacterial metabolism

The physiological nature of its constituents guarantees complete tolerability

# KOURILES

## Emulsion and Shampoo

Sebomine components

### **GLUCO-OXIDASE**

When skin metabolism processes glucose pentacetate into glucose and water, gluco-oxidase promotes the formation of hydrogen peroxide

### **LACTO-PEROXIDASE AND THIOCYANATE**

Newly formed hydrogen peroxide takes part to the reaction in which lacto-peroxidase converts thiocyanate into hypothiocyanate.

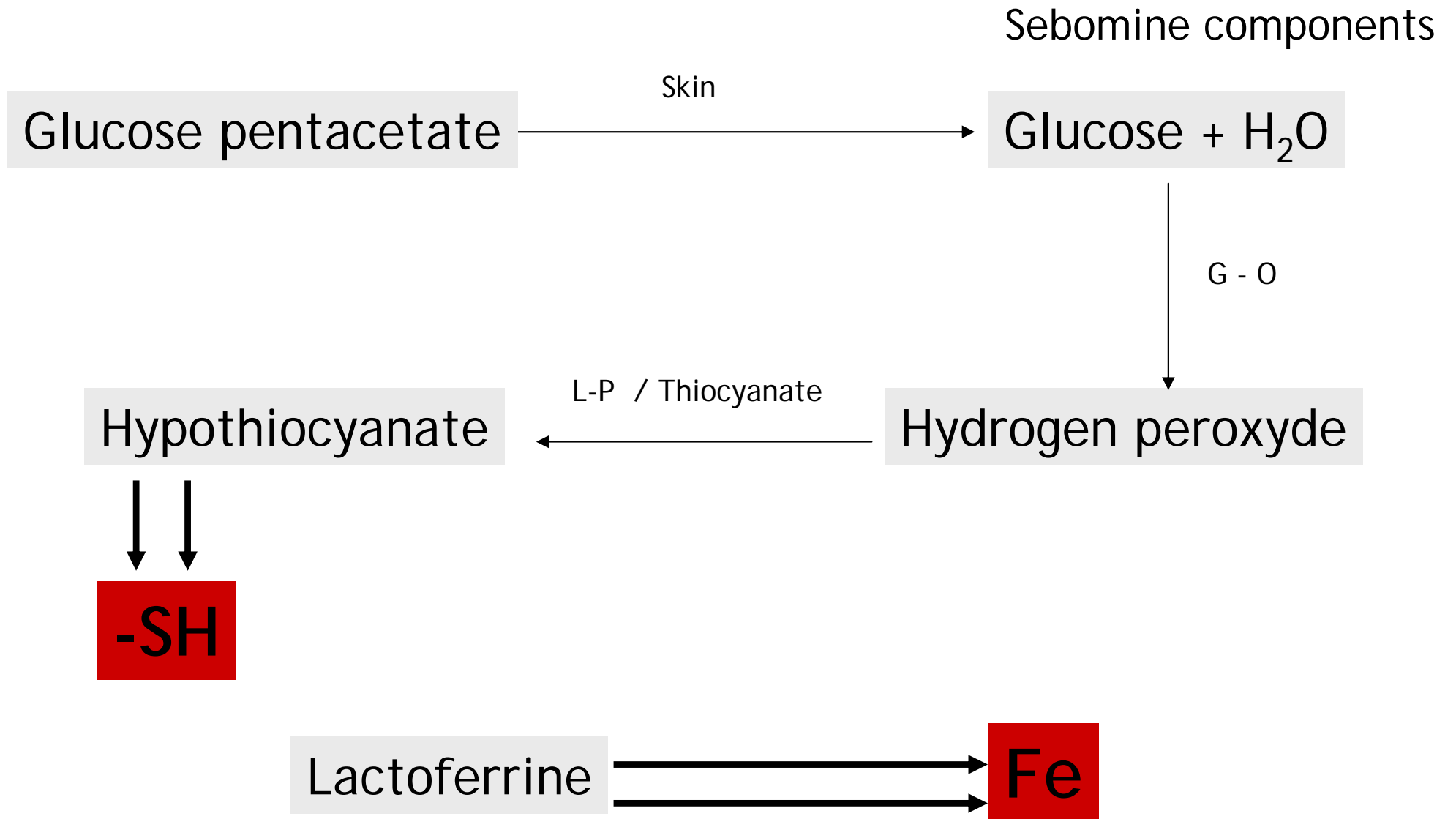
Hypothiocyanate reduces fungal and bacterial sulfuric groups exerting anti-microbial action

### **LACTOFERRINE**

Lactoferrine rapidly chelates iron, a vital mineral for microbial metabolism

# KOURILES

## Emulsion and Shampoo



H.U.C.P.

H.U.C.P. is a specific molecular weight hyaluronic acid  
internationally patented by Farmaka

Normally present in human derma, this mucopolysaccharide  
plays many roles in the skin: as part of cellular matrix, allowing  
intercellular exchanges and acting as a physical barrier to pathogens

Farmaka's H.U.C.P. has the capacity to physically protect  
hair follicles against the harmful action of DHT.

One of DHT's actions is to promote excessive sebum secretion.

In clinical trials H.U.C.P showed powerful superficial and deep hydration.



# KOURILES

## Emulsion and Shampoo

Norgel

Norgel is a glycerin and polymethacrylic acid ester capable to bind great amounts of water.

When Norgel is applied on the skin it rapidly releases water, producing high hydration

Norgel's efficacy in binding water brought another advantage to Kouriles emulsion: a formulation with no added preservatives

# KOURILES

## Emulsion and Shampoo

### KOURILES Emulsion : efficacy

Kouriles has been specifically formulated to treat every aspect of seborrheic dermatitis.

Antimicrobial components fight infection, the primary cause of inflammation. Octopirox and deep hydrating compounds reduce scaling

Every Kouriles component has been chosen to be effective yet perfectly tolerated

The absence of added preservative and perfume makes Kouriles emulsion a viable choice in the treatment of seborrheic dermatitis and cradle cap

# KOURILES

## Emulsion and Shampoo

### KOURILES : new indications

Lately Farmaka carried out a new clinical trial on Kouriles emulsion.

The main objective of this trial is to gather evidence that Kouriles is effective in the treatment of atopic skin (eczema).

Atopic skin's most common symptoms are dry, itchy skin; cracks behind the ears, rashes on the cheeks, arms, and legs.

The skin of a person with atopic dermatitis loses too much moisture from the epidermal layer, allowing the skin to become very dry and reducing its protective abilities.

In addition, the patient's skin is very susceptible to recurring infections

# KOURILES

## Emulsion and Shampoo

KOURILES : new indications

20 subjects with atopic skin have been treated with Kouriles emulsion twice a day for 30 days.

Periodical controls being held at day 0, day 15 and day 30.

The trial has been designed keeping in mind the most relevant symptoms of atopic skin:

**Erythema**

**Scaling**

**Trans epidermal water loss (TEWL)**

**Skin hydration**

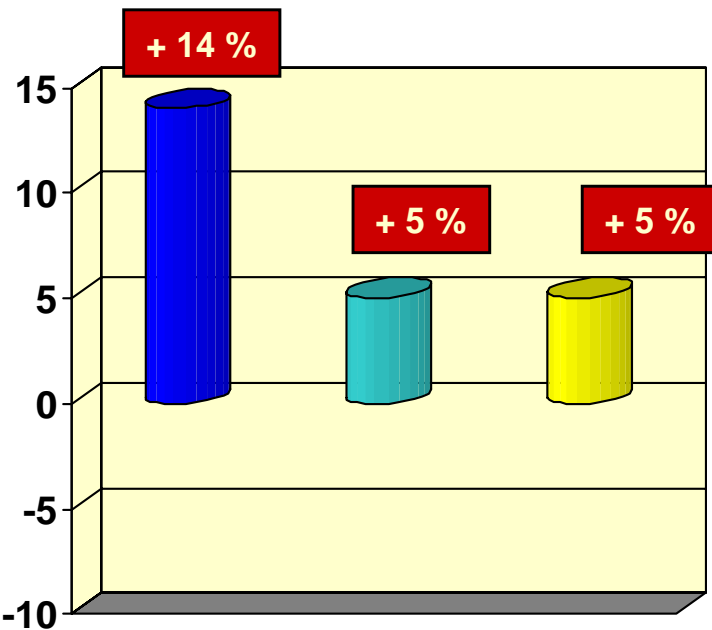
# KOURILES

## Emulsion and Shampoo

KOURILES : new indications

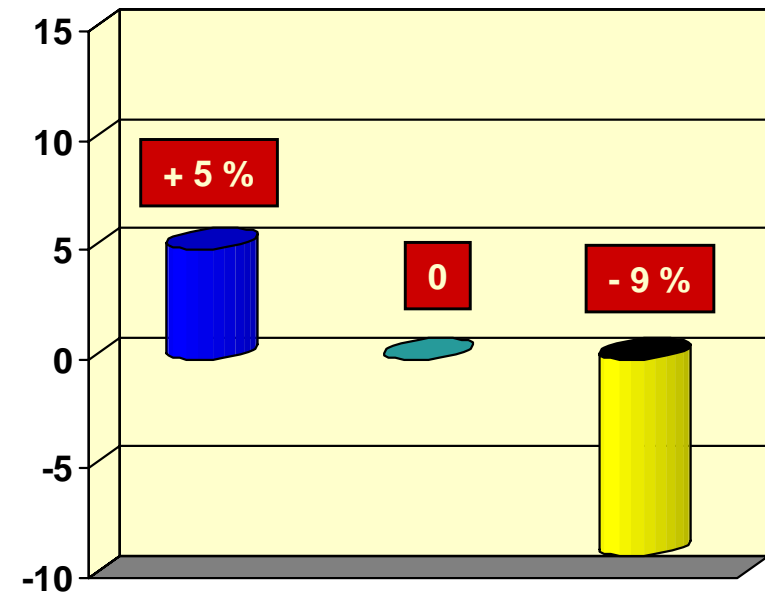
Erythema: - 25%

*After 8 hours*



*After 24 hours*

■ Control  
■ Pre-treated area  
■ Post treated area

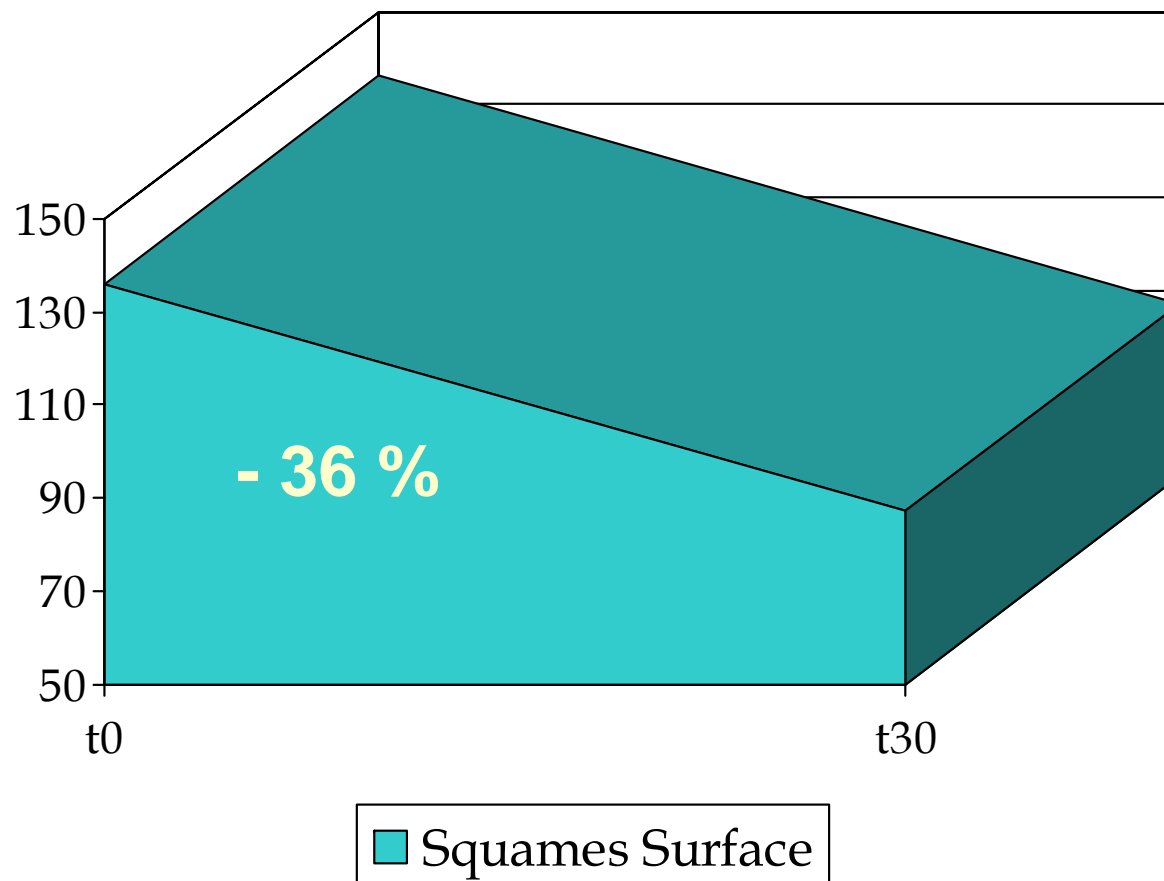


# KOURILES

## Emulsion and Shampoo

KOURILES : new indications

**Scaling: - 36%**

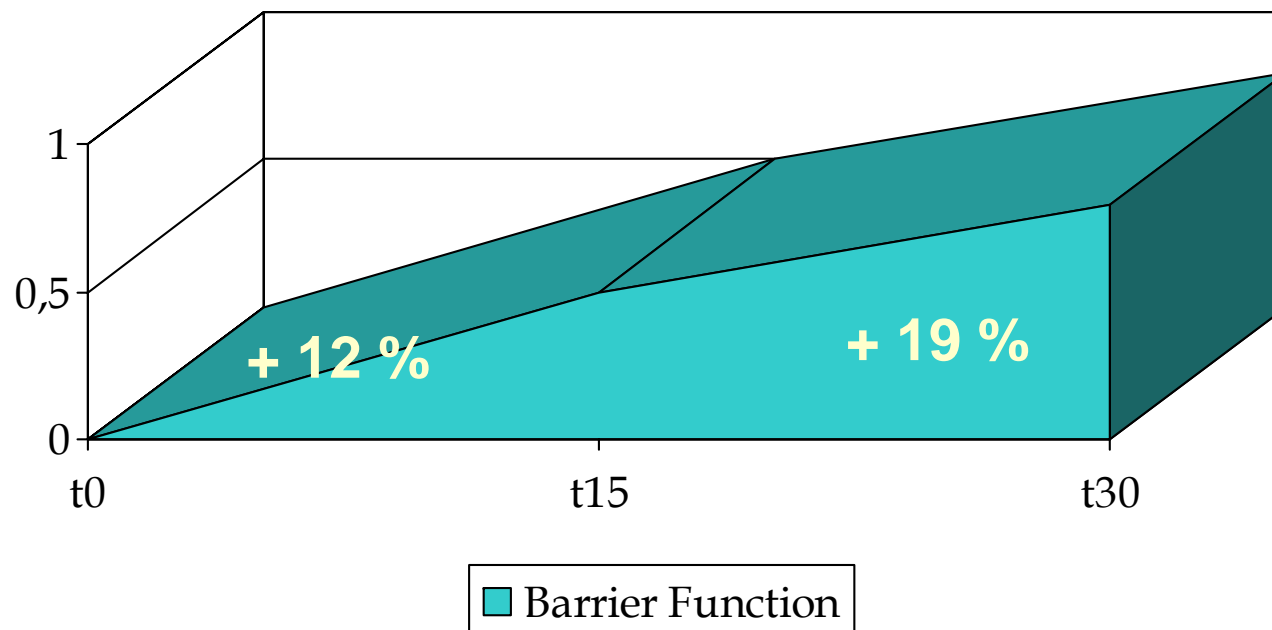


# KOURILES

## Emulsion and Shampoo

KOURILES : new indications

**Improved skin barrier function: +19%**

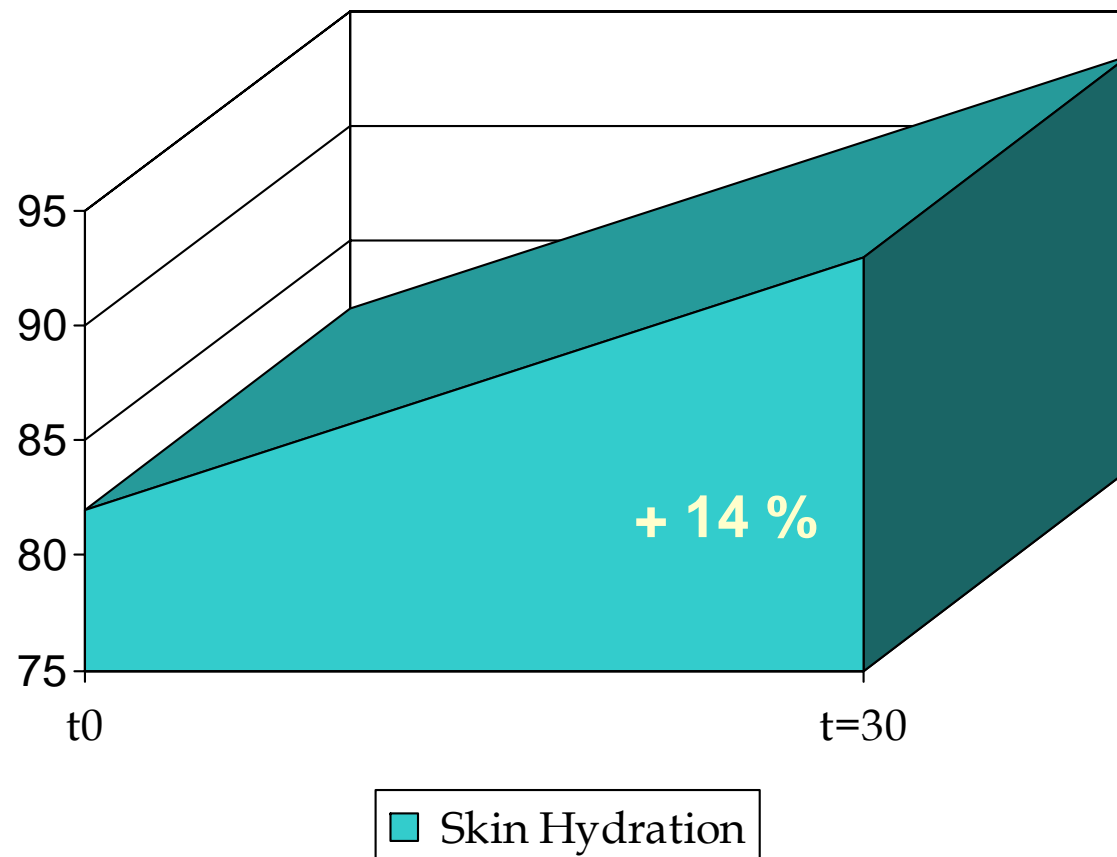


# KOURILES

## Emulsion and Shampoo

KOURILES : new indications

**Skin hydration: +14%**





# KOURILES

## Emulsion and Shampoo

### KOURILES Shampoo

#### ACTIVE PRINCIPLES

#### ACTION

Climbazole



Anti-mycotic

Phlorogine



Anti-sebum

H.U.C.P.



Dermal protection

Vitamine E



Anti-oxidant

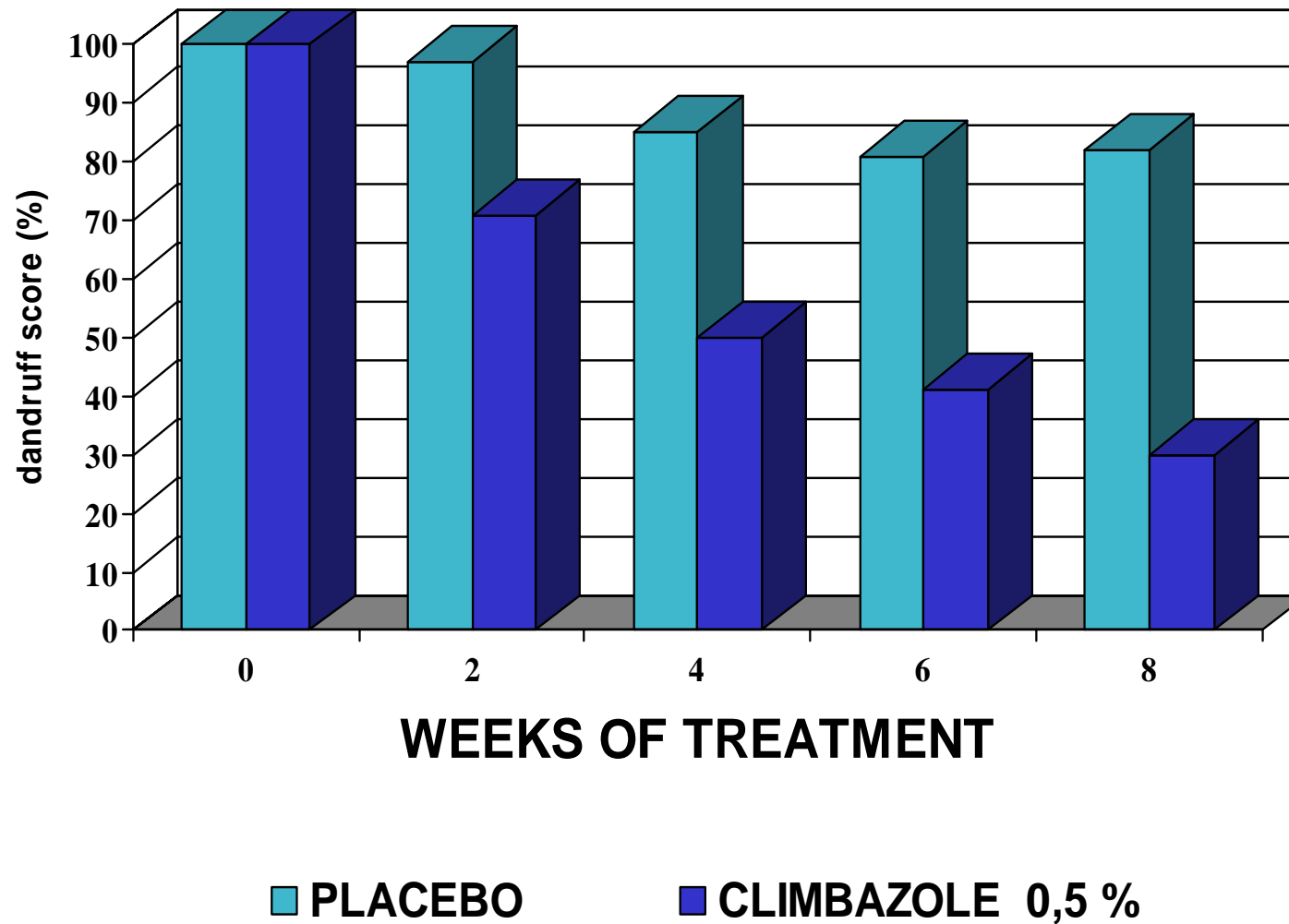
Imidazoles are the anti-mycotic **drugs of choice** for the treatment of topical and systemic fungal infections

Although being equally effective than its more popular competitor ketoconazole, climbazole is **much better tolerated** than the former

# KOURILES

## Emulsion and Shampoo

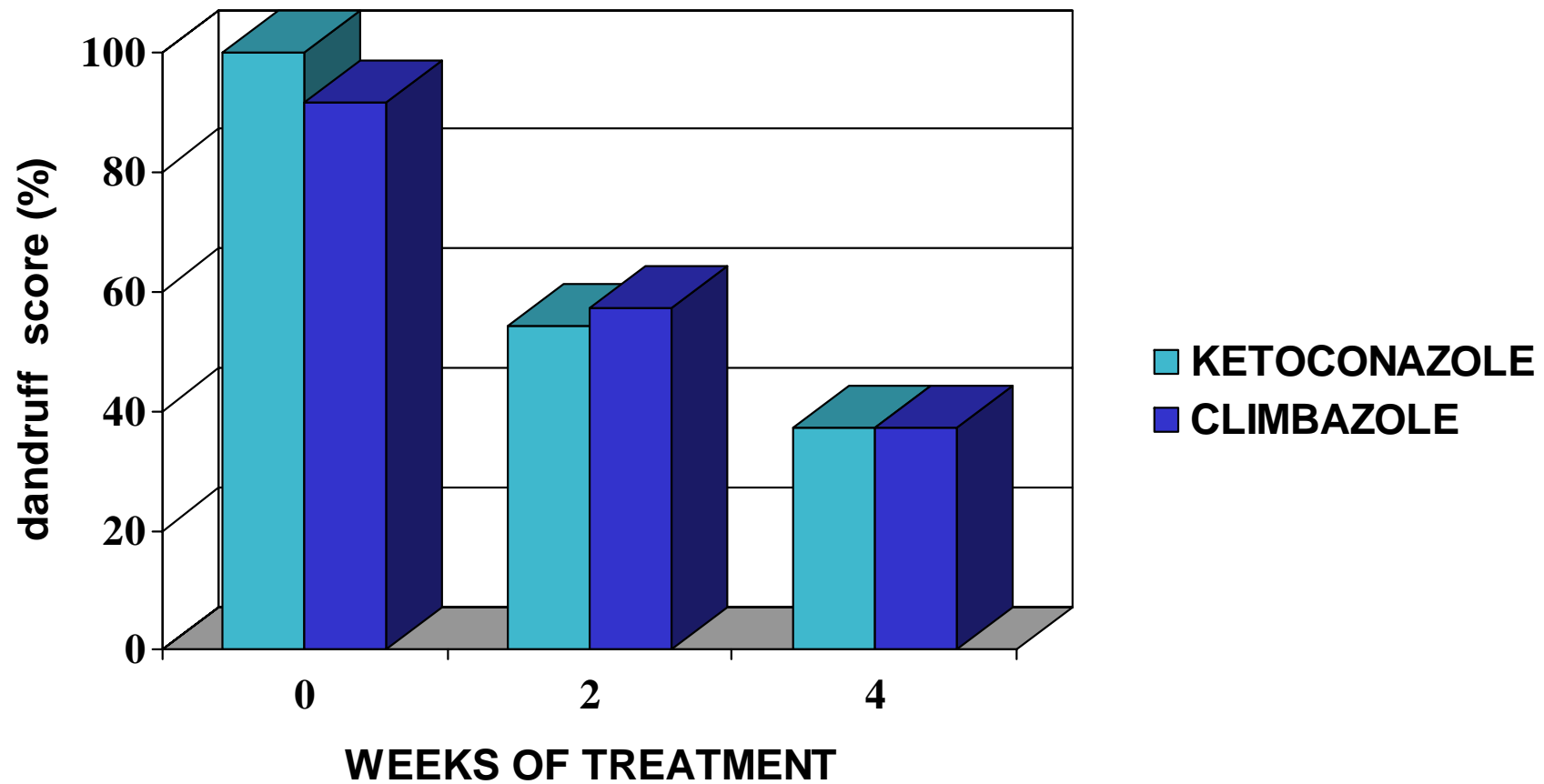
Climbazole



# KOURILES

## Emulsion and Shampoo

Climbazole

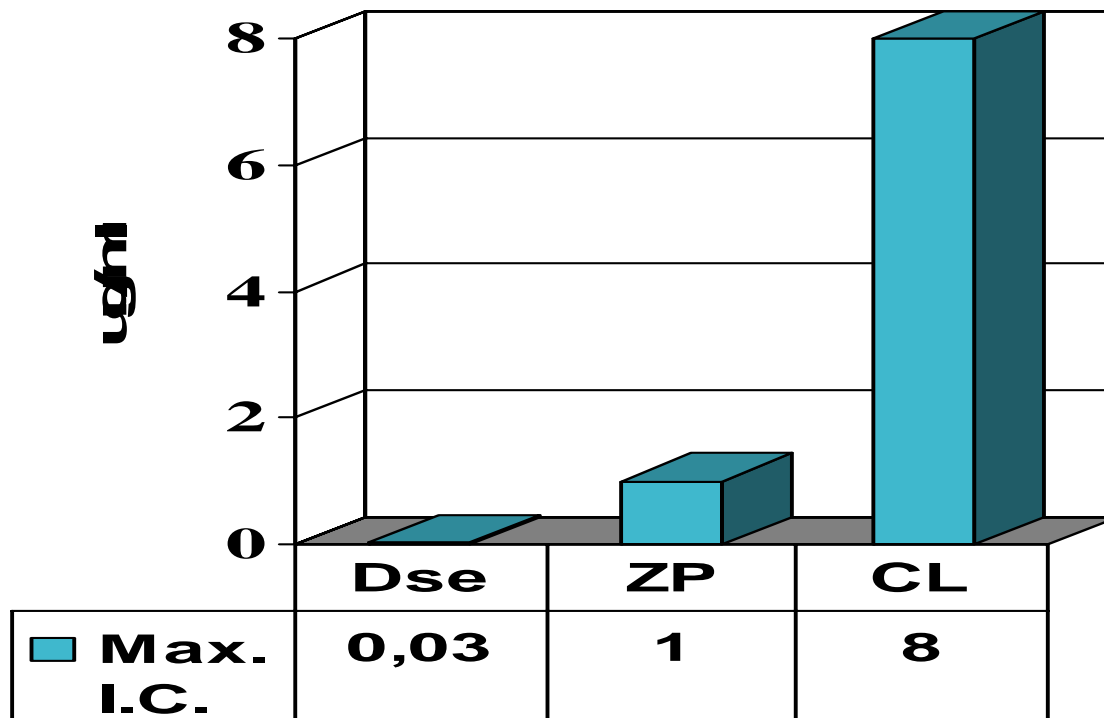


# KOURILES

## Emulsion and Shampoo

Climbazole

*Climbazole is harmless to skin flora*



# KOURILES

## Emulsion and Shampoo

### Phlorogine

Phlorogine is Extracted from the  
alga *Laminaria Saccharina*

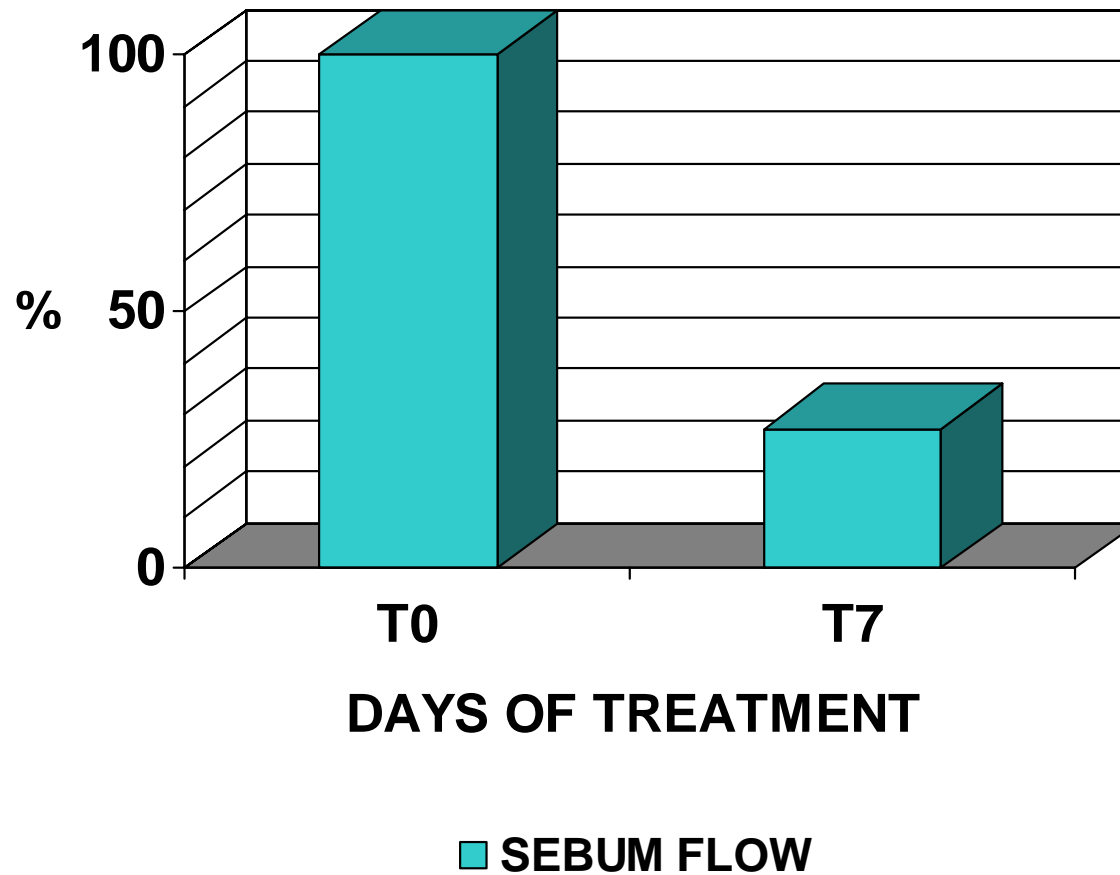
Clinical data shows that phlorogine  
can reduce sebum flow  
and exert anti-lipase action  
thus inhibiting the microbial  
activity that causes inflammation



# KOURILES

## Emulsion and Shampoo

Phlorogine

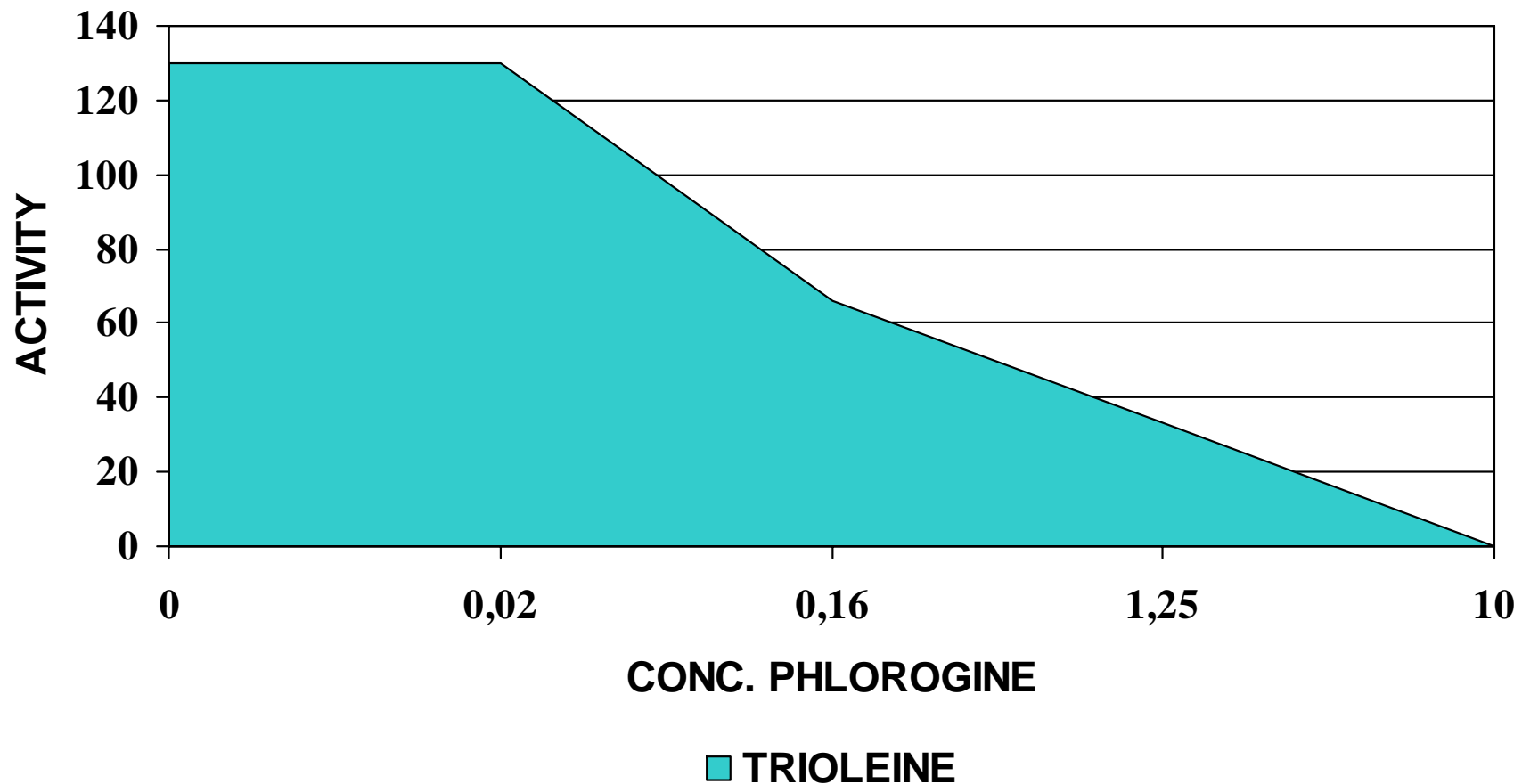


# KOURILES

## Emulsion and Shampoo

Phlorogine

*Lipase inhibiting action*





# KOURILES

## Emulsion and Shampoo

### KOURILES Shampoo : other features

Kouriles shampoo contains also vitamin E and H.U.C.P.

Vitamin E is a well known antioxidant that fights the formation of lipoperoxides which are produced during sebum degradation and increase skin irritation

H.U.C.P. , as previously mentioned, provides great dermal hydration while protecting hair follicles from DHT

Kouriles shampoo cleaning base is a balanced mixture of extra mild tensioactives such as sodium laureth sarcosinate and cocamide DEA.

All ingredients were specifically selected to prevent and cure skin irritation

# KOURILES

## Emulsion and Shampoo

*H.U.C.P. - Phlorogine*

HYPERKERATOSIS  
SEBORRHEA



SCALING

*Octopirox - Norgel*  
*H.U.C.P.*



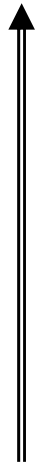
FUNGI  
INFECTION

*Climbazole - Sebomine*



**SEBBORRHEIC  
DERMATITIS**

*Kouriles*  
*Emulsion-Shampoo*



INFLAMMATION



# KOURILES

## Emulsion and Shampoo

### Clinical Trials : Emulsion

Clinical trials have been carried out in  
Italy, France and Spain on more than 300 patients.

Studio per la valutazione dell'efficacia di un'emulsione fluida per il trattamento della dermatite seborroica del cuoio capelluto e delle zone cutanee limitrofe.

L. Celleno - Università di Roma

Single blind controlled multicenter clinical trial for the evaluation of safety, efficacy and patients compliance using KVDS cosmetic lotion indicated for the treatment of seborrheic dermatitis of scalp and face.

Italy /France

Etude comparative de l'efficacité de KVDS dans le traitement de la dermatite séborréique de cuir chevelu, de sa lisiere et du visage.

Hop. S. Louis - Paris

Farmaka Srl - 2005

# KOURILES

## Emulsion and Shampoo

### Clinical Trials : Emulsion

Controlled open clinical trial for the evaluation of safety and efficacy of Kouriles Fluid Emulsion indicated for the treatment of seborrheic dermatitis of the scalp in neonates and infants.

R. Di Vincenzo, E. Prina

Efecto de la aplicacion topica del producto KOURILES emulsion en el tratamiento del eccema seborreico.

J. Noguera et al. - Barcelona

Efecto de la aplicacion de KOURILES Emulsion Fluida en el tratamiento de la Dermatitis Seborreica.

E. R. Rodriguez - Madrid

# KOURILES

## Emulsion and Shampoo

### Clinical Trials : Shampoo

Clinical trials have been carried out in Italy and Spain on more than 60 patients.

Studio di efficacia e tollerabilità dello shampoo Kouriles.

C. Pelfini - St. Anna Hospital - Como - Italy

Efecto de la aplicacion del producto Champù KOURILES en el tratamiento de la dermatitis seborreica.

E. R. Rodriguez - Madrid

# KOURILES

## Emulsion and Shampoo

Marketing

Kouriles has been formulated to counter all the symptoms of seborrheic dermatitis

Every aspect of this multifactorial skin condition, from its primary cause to its unpleasant symptoms were focused

Kouriles is a cosmeceutical: a cosmetic product with solid clinical evidence on both its efficacy and safety

# KOURILES

## Emulsion and Shampoo

Marketing

Kouriles emulsion is clearly a viable choice in the treatment of dry, scaling, eczematous skin

Clinical data shows that Kouriles can **complement** or **replace** the use of drugs of choice in treating seborrheic dermatitis and symptoms of other dermatitis

# KOURILES

## Emulsion and Shampoo

Marketing

**Kouriles is marketed worldwide:**

Italy	by Abiogen
Spain	by Laboratorios Thea
Poland	by CSC
Greece	by Lavipharm
Denmark	by AnaGen as
Norway	by AnaGen as
Sweden	by AnaGen as
China	by Manna Taiji

(and other Eastern European countries) Farmaka Srl - 2005