

**IN VITRO Ltd.**  
H-2120 Hungary,  
Dunakeszi, Repülőtéri út 1i.

## **CLINICAL REPORT**

*Title of the study*

**Use of PSORIT-X cream shampoo in psoriasis  
capitis and seborrhoea capitis**

*Study site*

**Semmelweis University, Clinic of Dermatological and  
Sexually Transmitted Diseases**

*Address:* H-1085 Hungary, Budapest, Mária utca 41.

*Tel.:* 36-1-266-04-65

*Study director*

**Prof. Dr. Attila Horváth, director of the Clinic of  
Dermatological and Sexually Transmitted Diseases**

*Sponsor of the study*

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## Chapter 1

### Summary

PSORIT-X cream shampoo is a new remedy for the treatment of seborrhoea capitis (seborrhoea of the scalp) and psoriasis capitis (psoriasis of the scalp). PSORIT-X cream shampoo contains four different groups of active ingredients in a lipophilic vehicle. These groups include: 1./ Propolis; 2./ Natural (sea) salt; 3./ Extracts from 13 medicinal plants widely used in dermatology and cosmetology; 4./ Vitamins (d-panthenol and vitamin-E). The active ingredients of PSORIT-X have been applied in the past and present for the treatment of psoriasis separately in many different preparations of different manufacturers. These groups of ingredients are unified in PSORIT-X in order to benefit from their synergistic effects.

PSORIT-X is from technological point of view not an usual shampoo but as above indicated a cream shampoo. It contains active ingredients exclusively of natural origin in an unique composition and in high concentration achieved by specific pharmaceutical technological manufacturing procedures. It has highly concentrated active ingredients and small water content. When used, the skin of the scalp does not become dry and at the same time the sebaceous (fatty) secretion of the scalp gets reduced. The pH of the cream shampoo is 5,5 which is in the same range with the skin's natural pH value.

In order to verify PSORIT-X cream shampoo's effect and safety in the clinical practice, IN VITRO Ltd. performed an open clinical study with 40 patients, 20 of them having seborrhoea capitis and 20 having psoriasis capitis.

During the study there was a 2 week long wash-out period what was followed by a 3 week long administration of the shampoo. The total time of the study was 5 weeks. During the study 4 medical examinations (rounds) took place (1<sup>st</sup> round: 2 weeks (wash out period); 2<sup>nd</sup> round: 0. week (starting point); 3<sup>rd</sup> round: 1<sup>st</sup> week; 4<sup>th</sup> round: 3<sup>rd</sup> week). Patients used PSORIT-X cream shampoo for their daily hairwash for 1 week, then as needed.

The evaluation was performed according to a 4-score (0, 1, 2, 3) scale representing the severity of symptoms. The studied parameters in psoriasis capitis included parakeratosis, infiltration, erythema and itching, while in seborrhoea capitis desquamation, inflammation, fatty hair and itching.

There was a subjective evaluation of PSORIT-X cream shampoo, too, made by the patients and their doctors using 3 categories: excellent effect, good effect, no effect.

The results support the previous observations that PSORIT-X cream shampoo can be successfully applied in seborrhoea capitis to reduce desquamation, inflammation, fatty hair and itching and in psoriasis capitis to decrease parakeratosis, infiltration, erythema and to a smaller extent itching which are

four key symptoms of psoriasis capitis. The beneficial effects appear quickly, after one week of treatment.

Results of the subjective evaluation of patients on efficacy of the treatment showed that the majority of the patients considered the efficacy of the treatment to be either good or excellent. The doctor's evaluation showed the same results.

## Chapter 2

### Introduction

**Seborrhoea** is a very frequent dermatological disease with an inherited element, characterized basically by hypersteatosis (increased production of sebum). Seborrhoea usually begins in the teenage years and is more frequent in men than in women. Characteristic for this disease the fatty skin of the face, the desquamation, pityriasis and the inflammation, the infiltration and the fatty hair. In the treatment of seborrhoea hair-cleaning preparations with the capacity to normalize sebum production provide benefit.

**Psoriasis** is a chronic, inflammatory skin disorder that affects millions of people all over the world, although its incidence depends on geographical and ethnic factors. Its incidence in the developed countries is about 2% of the population. No one knows exactly what causes this disease, although recent medical thinking holds that it is an immune-mediated disorder.

There are various forms of psoriasis. Psoriasis can be limited to a few plaques or can involve moderate to extensive areas of skin. Psoriasis can range from mild to moderate to very severe and disabling. However, for most people, psoriasis tends to be mild. Some people experience spontaneous, transitory remissions, but no one knows why this happens and they are unpredictable.

Most commonly the scalp, knees, elbows, hands and feet are affected by the disease. It rarely affects the face. However, no area of the skin is exempt, including the genital area. Infiltration and parakeratosis are characteristic. In psoriasis of the scalp (psoriasis capitis) seborrhoea is the most important provoking factor.

Both males and females get psoriasis in equal numbers. It can strike at any age, but most often between 15 and 35 years.

There is no medical test for psoriasis. The doctor makes the diagnosis after observing the skin, and studying the psoriatic plaque cells under a microscope. There is no cure at the moment, but there are many different treatments, both topical and systemic, that can clear psoriasis for periods of time. Experimentation is often required to find a treatment that works for a particular person. Every treatment improving seborrhoea as provoking factor, has the potential to improve psoriasis as well. Successful treatment of the scalp lesions can be very difficult.

Against psoriasis there are active agents of strong pharmacological effect like steroids, retinoids, psoralen, calcipotriol. These agents, especially steroids can be very effective, but at a cost of disturbing, sometimes very serious side

effects. Therefore, there is a great need for effective but mild and safe remedies.

PSORIT-X cream shampoo is a new remedy against seborrhoea and psoriasis of the scalp which to a large extent fulfills the above requirements.

PSORIT-X cream shampoo contains a combination of different active ingredients of natural origin as follows:

1. Propolis: complex composition: volatile oils, balsams, flavones, mineral substances, etc. Originates from saps of different plant's buds, twigs and leaf-stalks collected by bees.

*Propolis used in the manufacturing of PSORIT-X cream shampoo is produced by a special technological procedure eliminating the possible allergenic components.*

2. Sea-salt: sodium, potassium, selenium, chloride, fluoride, iodide, etc.)

3. Medicinal plants:

- Thyme (*Thymus vulgaris* L.)
- Lemon (*Citrus medica* L. var. Limonum)
- Tea tree (*Melaleuca alternifolia*):
- Chamomile (*Matricaria chamomilla* L.)
- Yarrow (*Achillea millefolium* L.)
- Dill (*Anethum graveolens* L.)
- Parsley (*Petroselinum crispus*)
- Great nettle (*Urtica dioica* L.)
- Calendine (*Chelidonium majus* L.)
- Oak (*Quercus robur* L.)
- Willow (*Salix alba* L.)
- Marigold (*Calendula officinalis* L.)
- Dandelion (*Taraxacum officinale* Web.)

4. Vitamins: d-panthenol, vitamin E

As demonstrated by the above data, PSORIT-X cream shampoo contains 21 active ingredients in a lipophilic vehicle. The special composition of PSORIT-X (via its surface-active compounds) ensures that the loss of fat from the hair during hairwash is substituted, preventing the dehydration of the scalp and the hair. PSORIT-X cream shampoo contains exclusively ingredients of natural origin. Synthetic odorants are excluded. The pH of the preparation is 5.5 which is in the same range with the skin's natural pH value.

All the above substance-groups and their representatives have been separately applied in different preparations against psoriasis, seborrhea and other skin problems or simply in many cosmetics. They contain compounds of antiseptic and anti-inflammatory effect.

The idea behind PSORIT-X cream shampoo is to combine these ingredients in one preparation in order to help each other's effect in the symptomatic treatment of psoriasis and seborrhea capitis (seborrhea of the scalp)

The complex composition was a challenge from pharmaceutical technological/manufacturing point of view, too, which has been successfully solved.

The cream shampoo has the unique characteristic of carrying anti-inflammatory and antiseptic ingredients, and at the same time supplying lipids (fats) to the skin.

After the development of PSORIT-X cream shampoo, this preparation has been used by thousands of seborrhoeic and psoriatic patients (in seborrhea capitis and/or psoriasis capitis) in different countries, usually with very positive results. However, these are case reports and the developer company, IN VITRO Ltd. decided to perform clinical studies in order to scientifically support the efficacy and safety of PSORIT-X cream shampoo.

### **Chapter 3**

#### **Aim of the study**

Scientific examination of effects, side effects and safety of PSORIT-X cream shampoo in symptoms of psoriasis capitis and seborrhoea in an open clinical study.

### **Chapter 4**

#### **Study protocol**

##### *Title of the study*

Use of PSORIT-X shampoo in psoriasis capitis and seborrhoea capitis

##### *Study site*

Semmelweis University, Clinic of Dermatological and Sexually Transmitted Diseases, H-1085 Hungary, Budapest, Mária utca 41.; Tel.: 36-1-266-04-65

##### *Study director*

Prof. Dr. Attila Horváth, director of the Clinic of Dermatological and Sexually Transmitted Diseases

##### *Sponsor of the study*

IN VITRO Ltd.

H-2120 Hungary, Dunakeszi, Repülőtéri út 1; Tel.: +36 27 392 489, fax: +36 27 341-751

### *Participants to be involved*

- Patients with psoriasis capitis or seborrhoea capitis
- Age: patients of both sexes above 18 years
- Patients not receiving systemic antipsoriasis or antiseborrhoea treatment, or hormonal contraceptives within 3 months before the start of the study.
- Patient who signed the declaration on voluntary participation

### *Participants excluded from the study*

Excluded were from the study those, who

- received internal treatment (Neotigason, corticosteroids, cytostatic drugs) within 3 months before the start of the study
- women taking hormonal contraceptives
- known hypersensitivity to any of the components of the shampoo
- receiving other local antipsoriasis or antiseborrhoea treatment
- has not signed the declaration on voluntary participation
- demonstrated poor compliance

### *Number of enrolled patients:*

#### *Patients with seborrhoea capitis:*

N = 20 (11 women, 9 men)

#### *Patients with psoriasis capitis:*

N = 20 (15 women, 5 men)

### *Study design*

#### *Time span of the study:*

Wash out period: 2 weeks

Administration of the shampoo: 3 weeks

Total time: 5 weeks

#### *Date of rounds (medical examinations):*

1<sup>st</sup> round: 2 weeks (wash out period)

2<sup>nd</sup> round: 0. week (starting point)

3<sup>rd</sup> round: 1<sup>st</sup> week

4<sup>th</sup> round: 3<sup>rd</sup> week

#### *Total number of rounds: 4.*

Patients used during the wash-out period a neutral shampoo supplied by the sponsor of the study. They did not received any other concomitant antiseborrhoeic and/or antipsoriasis treatment neither during the wash-out period nor during the active treatment period.

*Frequency of use of PSORIT-X cream shampoo:* daily hairwash for 1 week, then as needed.

*Study medicine (batch number):*

- 07012003

- 12012003

*Packaging and labeling:* Packaging (plastic tube as primary and carton box as secondary (outer) packaging material) and labeling of the study medicine was identical to that of the commercial batches.

### *Evaluation of efficacy*

The evaluation is performed according to a 4-score (0, 1, 2, 3) scale

### *Studied parameters*

#### *A. Seborrhoea capitis*

|              |        |          |                  |             |
|--------------|--------|----------|------------------|-------------|
| Desquamation | 0= not | 1 = mild | 2 = medium-level | 3 = serious |
| Inflammation | 0= not | 1 = mild | 2 = medium-level | 3 = serious |
| Fatty hair   | 0= not | 1 = mild | 2 = medium-level | 3 = serious |
| Itching      | 0= not | 1 = mild | 2 = medium-level | 3 = serious |

### *Registration of possible side effects*

#### *B. Psoriasis capitis*

|               |        |          |                  |             |
|---------------|--------|----------|------------------|-------------|
| Parakeratosis | 0= not | 1 = mild | 2 = medium-level | 3 = serious |
| Infiltration  | 0= not | 1 = mild | 2 = medium-level | 3 = serious |
| Erythema      | 0= not | 1 = mild | 2 = medium-level | 3 = serious |
| Itching       | 0= not | 1 = mild | 2 = medium-level | 3 = serious |

### *Registration of possible side effects*

Symptoms are evaluated based on individual patient data sheets.

### *Evaluation of side effects*

### *Cosmetic effect/tolerability*

#### *A. Evaluation of the patients on the efficacy of the treatment:*

- no effect
- good
- excellent

*B. Evaluation of the doctors on the efficacy of the treatment:*

- no effect
- good
- excellent

*Would the patient later intend to use the study preparation?*

- yes
- not

## **Chapter 5.**

### **Results**

#### **A. Seborrhoea capitis**

*Patient description*

20 patients were enrolled in the study at visit 1 (11 woman, 9 men).

Data of 18 patients are included in the evaluation, because two patients dropped out:

1 patient (male) no reason

1 patient (male): contact dermatitis-like symptoms. In the epicutan allergy test he had hypersensitivity to fragrance mix and balsam of Peru.

The mean age of patients was 42,8 years (range 23 to 69 years)

No statistically significant difference was observed between age in the gender comparison.

*Evaluation of efficacy*

In the evaluation data of screening (visit 1 ) and data of baseline (visit 2) were compared.

No statistically significant difference was observed in visit 1 and visit 2 comparison of symptoms. This is logical and expected because between visits 1 and 2 the patients used not the study preparation, PSORIT-X cream shampoo but a neutral shampoo having no specific antiseborrhoeic and/or antipsoriasis effects.

The evaluation of the therapy was performed between visit 2 and visit 4, while the patients used the cream shampoo.

| Studied parameters | Visits (medical examinations)/average score of symptoms (1-3) |                 |                 |                 | Process of changing |
|--------------------|---|-----------------|-----------------|-----------------|---------------------|
|                    | 1 <sup>st</sup>   | 2 <sup>nd</sup> | 3 <sup>rd</sup> | 4 <sup>th</sup> |                     |
| Desquamation score | 1,94  | 2,11            | 0,83            | 0,5             | (p < 0,001)         |
| Inflammation score | 1,33  | 1,33            | 0,39            | 0,28            | (p < 0,001)         |
| Fatty hair score   | 1,94  | 1,94            | 0,83            | 0,56            | (p < 0,001)         |
| Itching score      | 2,33  | 2,28            | 0,78            | 0,72            | (p < 0,001)         |
| Summary score*     | 7,56  | 7,67            | 2,85            | 2,06            | (p < 0,001)         |

\*Summary score: summary of symptoms' score by patients

**Table 1.:** Evaluation of PSORIT-X cream shampoo's efficacy in seborrhoea capitis patients (n = 18 without the 2 drop-outs)

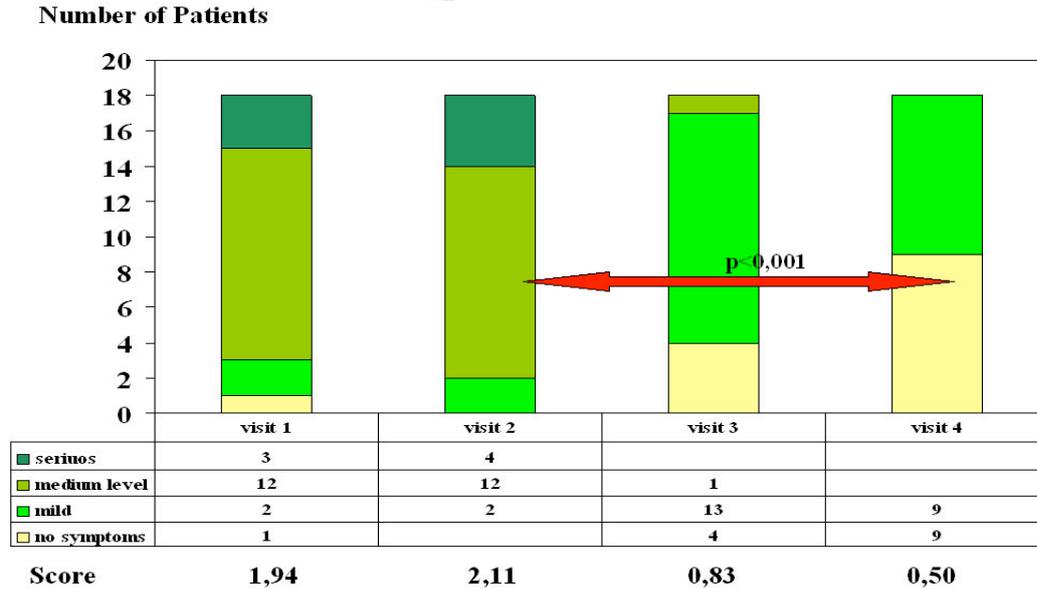
**Statistically significant difference was observed in visit 2 and visit 4 comparison of symptoms.**

**The following figures present the change of the 4 leading parameters of seborrhoea capitis in a more detailed form.**

### **A. Desquamation**

Desquamation is a characteristic symptom of seborrhoea capitis which causes among other things social stress (from aesthetic point of view) for the patients. As it can be seen from **Figure 1.**, the use of PSORIT-X cream shampoo significantly reduces the severity of desquamation and the number of symptomatic patients decreases, too.

## Symptoms of DESQUAMATION

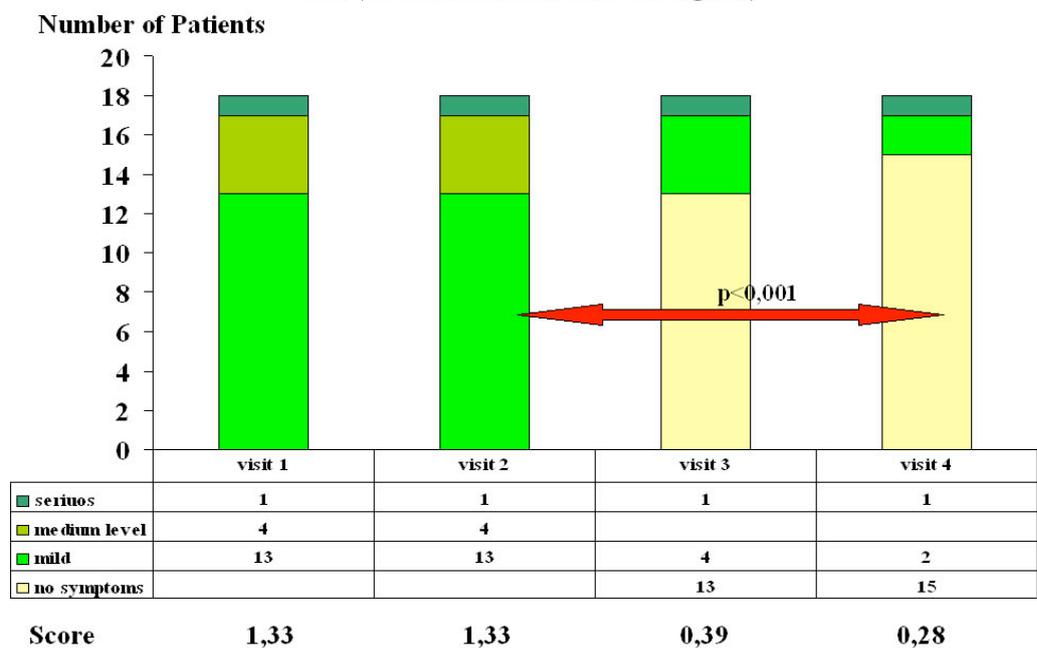


**Figure 1.:** Severity of desquamation in seborrhoea capitis patients as a function of PSORIT-X cream shampoo treatment

### B. Inflammation

Inflammation is also a characteristic symptom of seborrhoea capitis. As it can be seen from **Figure 2.**, both the severity and the incidence of inflammation decreases during the use of PSORIT-X cream shampoo. The reduction of severity reaches the level of significance.

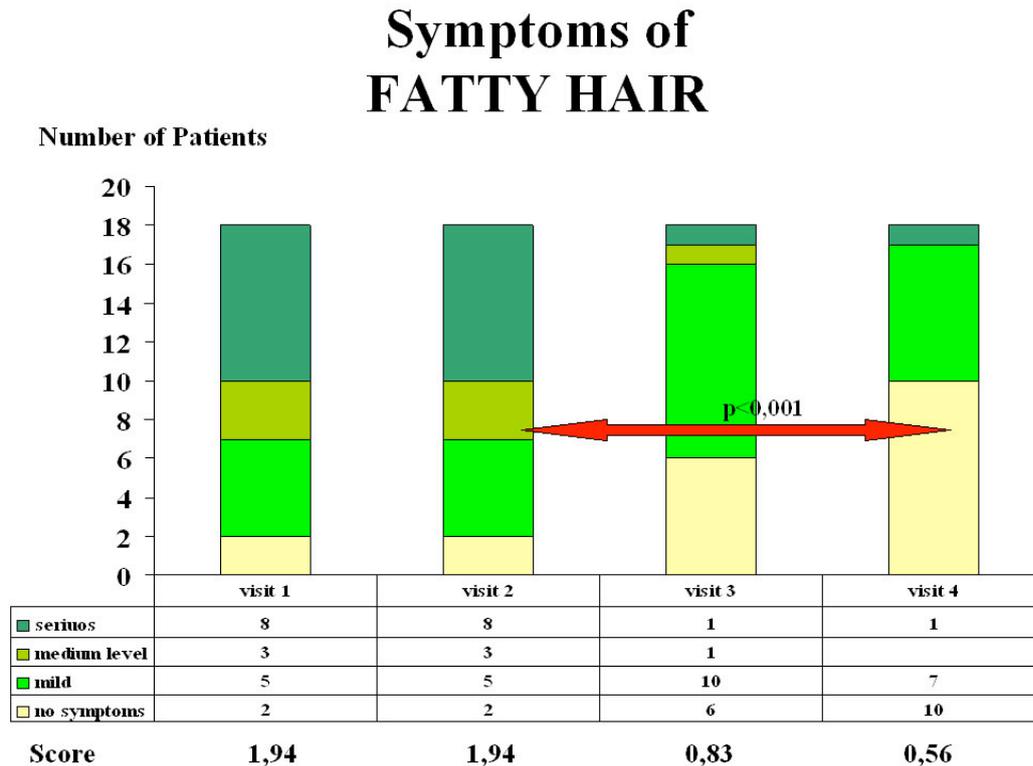
## Symptoms of INFLAMMATION



**Figure 2.:** Severity of inflammation in seborrhoea capitis patients as a function of PSORIT-X cream shampoo treatment

### C. Fatty hair

Fatty hair is a disturbing symptom of seborrhoea capitis. As it can be seen from **Figure 3.**, the use of PSORIT-X cream shampoo significantly reduces the fattiness of the scalp and the number of symptomatic patients decreases, too.

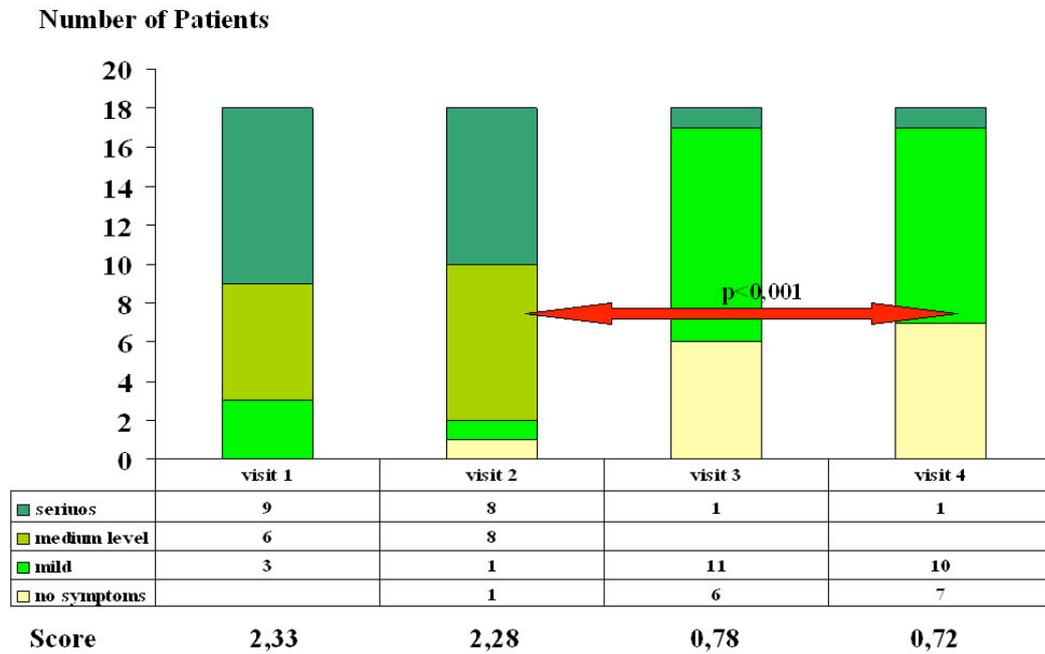


**Figure 3.:** Severity of fattiness of the scalp in seborrhoea capitis patients as a function of PSORIT-X cream shampoo treatment

### D. Itching

As it can be seen from **Figure 4.**, the use of PSORIT-X cream shampoo significantly reduces both the severity of itching of the scalp and the number of symptomatic patients.

# Symptoms of ITCHING

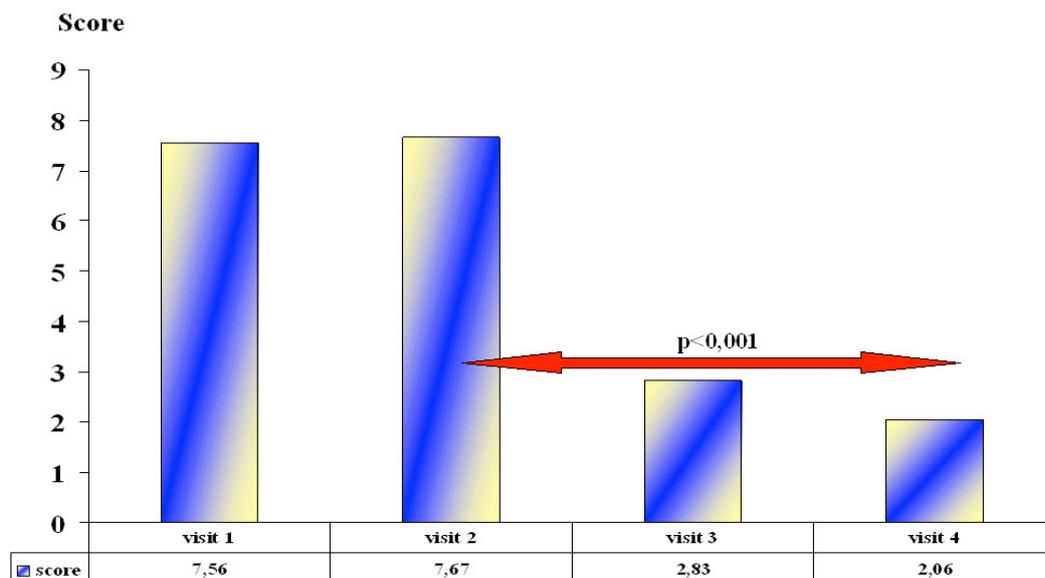


**Figure 4.:** Severity of itching of the scalp in seborrhoea capitis patients as a function of PSORIT-X cream shampoo treatment

## E. Summary of score of symptoms

The summary score of symptoms (see **Figure 5.**) shows that the combined scores of the examined parameters significantly decrease between visits 2 - 4.

## Summary Score of Symptoms



**Figure 5.:** Summary score of symptoms in seborrhoea capitis patients

*Cosmetic effect/tolerability*

A/ The patient's (subjective) evaluation on the efficacy of treatment (see **Figure 6.**)

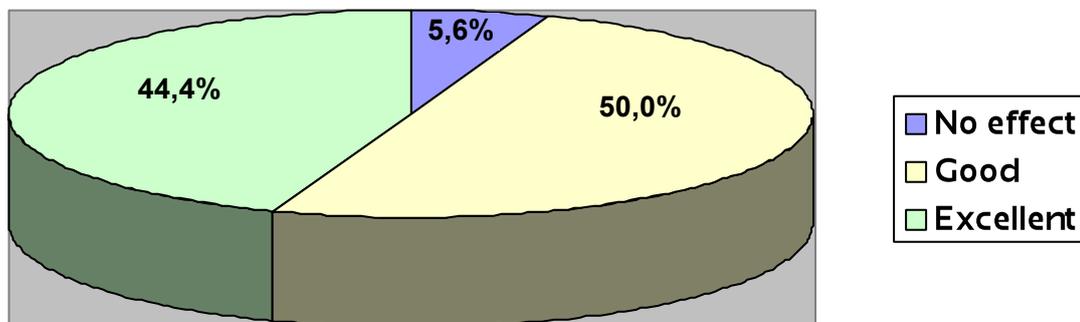
|           |                  |
|-----------|------------------|
| No effect | <b>5,6% (1)</b>  |
| Good      | <b>50% (9)</b>   |
| Excellent | <b>44,4% (8)</b> |

B./ The doctor's evaluation on the efficacy of treatment (see **Figure 7.**)

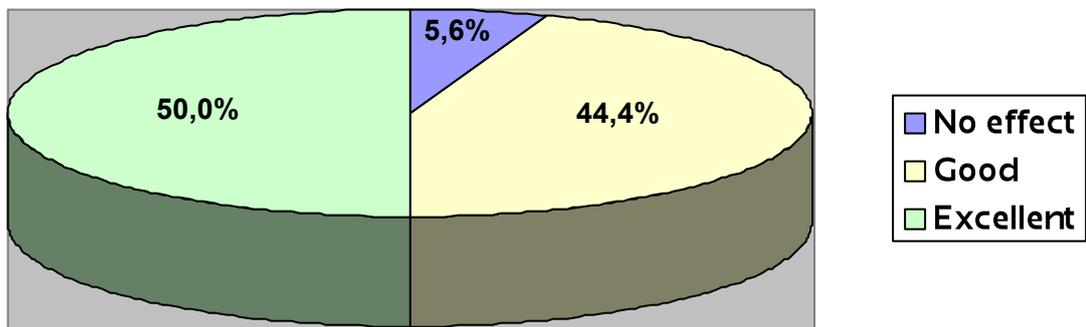
|           |                  |
|-----------|------------------|
| No effect | <b>5,6% (1)</b>  |
| Good      | <b>44,4% (8)</b> |
| Excellent | <b>50% (9)</b>   |

C./ Would the patient later intend to use the study preparation (see **Figure 8.**)?

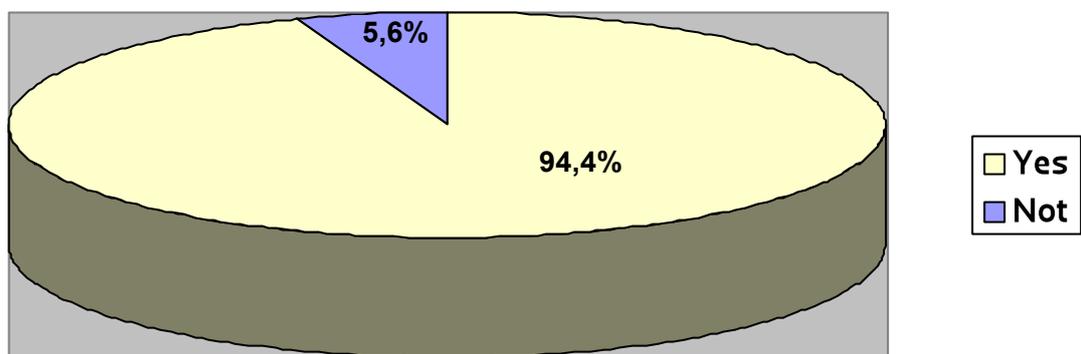
|     |                   |
|-----|-------------------|
| Yes | <b>94,4% (17)</b> |
| Not | <b>5,6% (1)</b>   |



**Figure 6.:** The patient's (subjective) evaluation on the efficacy of treatment



**Figure 7.:** The doctor's evaluation on the efficacy of treatment



**Figure 8.:** Would the patient later intend to use the study preparation?

*Possible side effects*

One male patient dropped out because of contact dermatitis-like symptoms. In the epicutan allergy test he had hypersensitivity to fragrance mix and balsam of Peru.

## B. Psoriasis capitis

### *Patient description*

20 patients were enrolled in the study at visit 1 (15 woman, 5 men).

Data of 19 patients are included in the evaluation, because one patient dropped out because of lack of time to take part in the study

The mean age of the patients was 46,5 years (range 19 to 75 years).

The mean age of the male patients was 65,4 years, whereas the mean age of the female patients was 39,8 years

### *Evaluation of efficacy*

In the evaluation data of screening (visit 1 ) and data of baseline (visit 2) were compared.

No statistically significant difference was observed in visit 1 and visit 2 comparison of symptoms. This is logical and expected because between visits 1 and 2 the patients used not the study preparation, PSORIT-X cream shampoo but a neutral shampoo having no specific antiseborrhoeic and/or antipsoriasis effects.

The evaluation of therapy was performed between visit 2 and visit 4, while the patients used the cream shampoo.

| Studied parameters  | Visits (medical examinations)/average score of symptoms (1-3) |                 |                 |                 | Process of changing (p < 0,001) |
|---------------------|---|-----------------|-----------------|-----------------|---------------------------------|
|                     | 1 <sup>st</sup>   | 2 <sup>nd</sup> | 3 <sup>rd</sup> | 4 <sup>th</sup> |                                 |
| Parakeratosis Score | 2,37  | 2,42            | 1,16            | 1,11            | (p < 0,001)                     |
| Infiltration score  | 2,16  | 2,21            | 1,37            | 1,26            | (p < 0,001)                     |
| Erythema Score      | 2   | 2,1             | 1,32            | 1,26            | (p < 0,001)                     |
| Itching score       | 1,11  | 1,0             | 0,68            | 0,74            | NS                              |
| Summary score*      | 7,63  | 7,74            | 4,53            | 4,37            | (p < 0,001)                     |

\*Summary score: summary of symptoms' score by patients

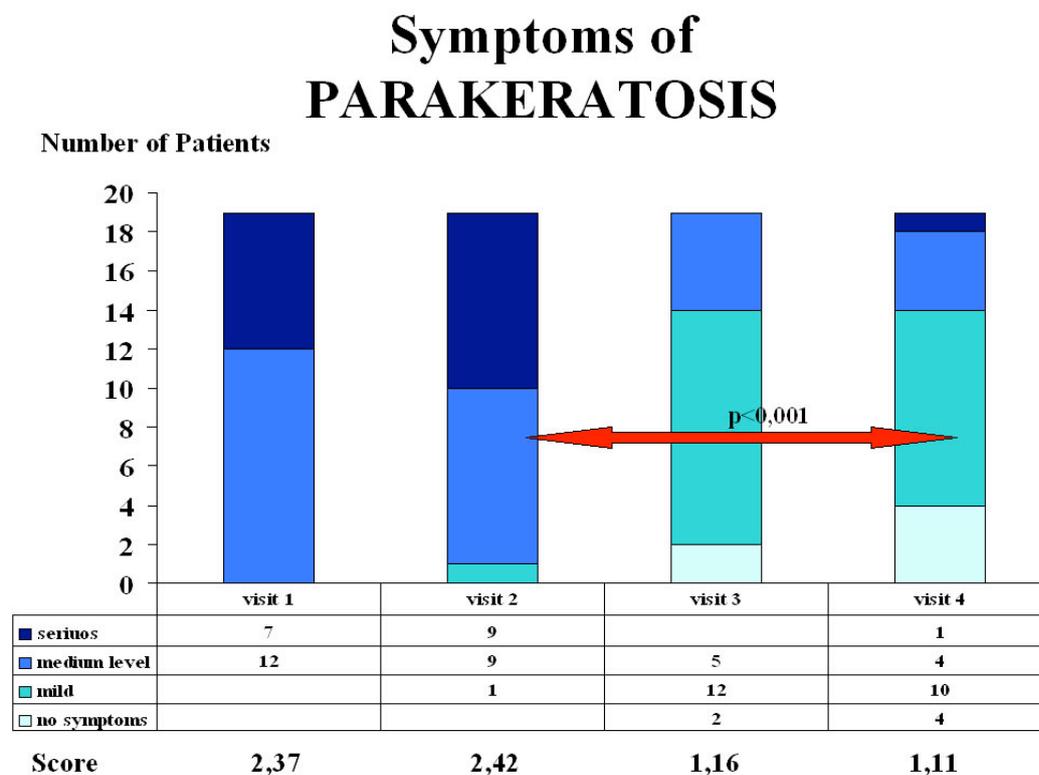
**Table 2.:** Evaluation of PSORIT-X cream shampoo's efficacy in psoriasis capitis patients (n = 19 without the 1 drop-out)

**Statistically significant difference was observed in visit 2 and visit 4 comparison of symptoms, with the exception of itching.**

**The following figures present the change of the 4 leading parameters of psoriasis capitis in a more detailed form.**

### A. Parakeratosis

Parakeratosis (a pathological form of keratinization) is very characteristic for psoriasis. This is a disturbing symptom for the patients which affects negatively their social life. As it can be seen from **Figure 9.**, the use of PSORIT-X cream shampoo significantly reduces the severity of parakeratosis.

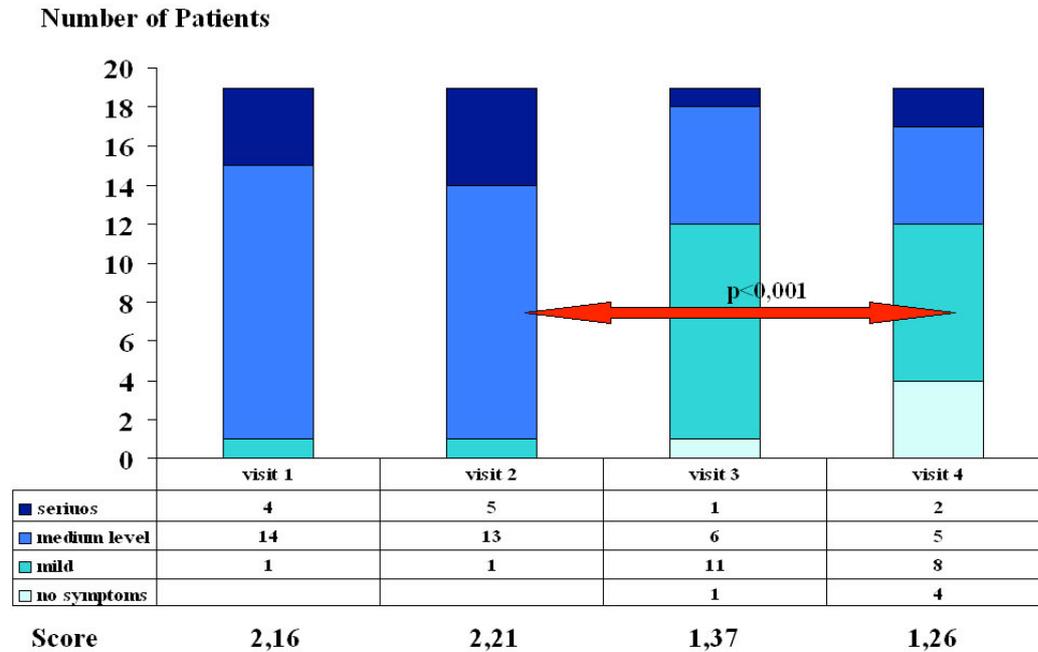


**Figure 9.:** Severity of parakeratosis in psoriasis capitis patients as a function of PSORIT-X cream shampoo treatment

### B. Infiltration

Infiltration is a symptom of inflammation involving with blood cells. As it can be seen from **Figure 10.**, the use of PSORIT-X cream shampoo significantly reduces the severity of infiltration.

## Symptoms of INFILTRATION

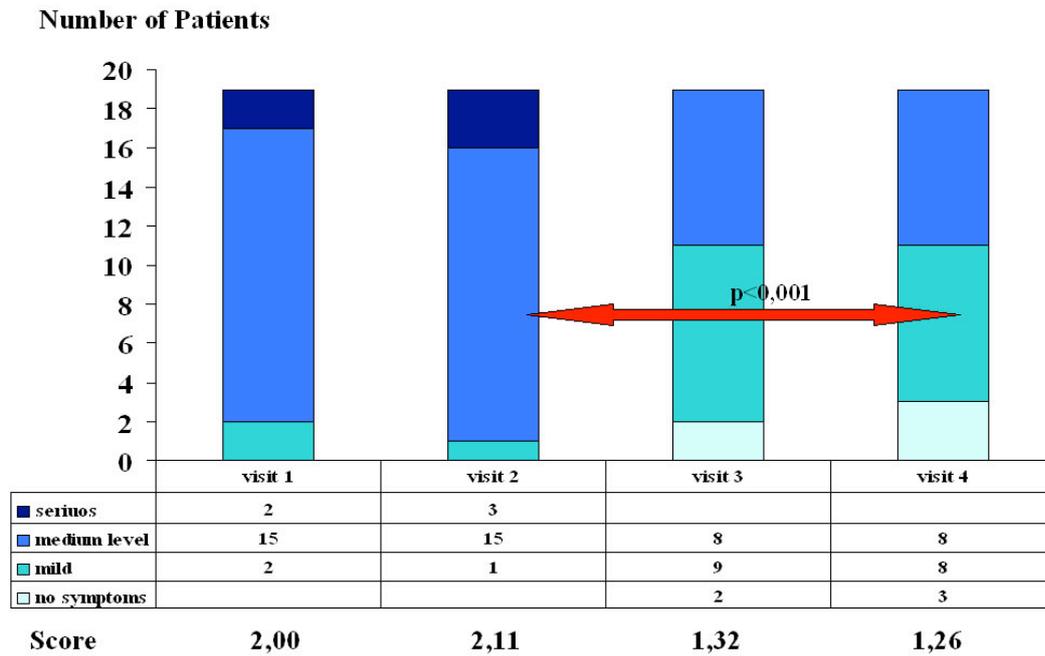


**Figure 10.:** Severity of infiltration in psoriasis capitis patients as a function of PSORIT-X cream shampoo treatment

### C. Erythema

The reddening of the skin (erythema) is caused by increased blood circulation. This symptom is in psoriasis a very visible sign of inflammation. As it can be seen from **Figure 11.**, the use of PSORIT-X cream shampoo significantly reduces the severity of erythema.

# Symptoms of ERYTHEMA

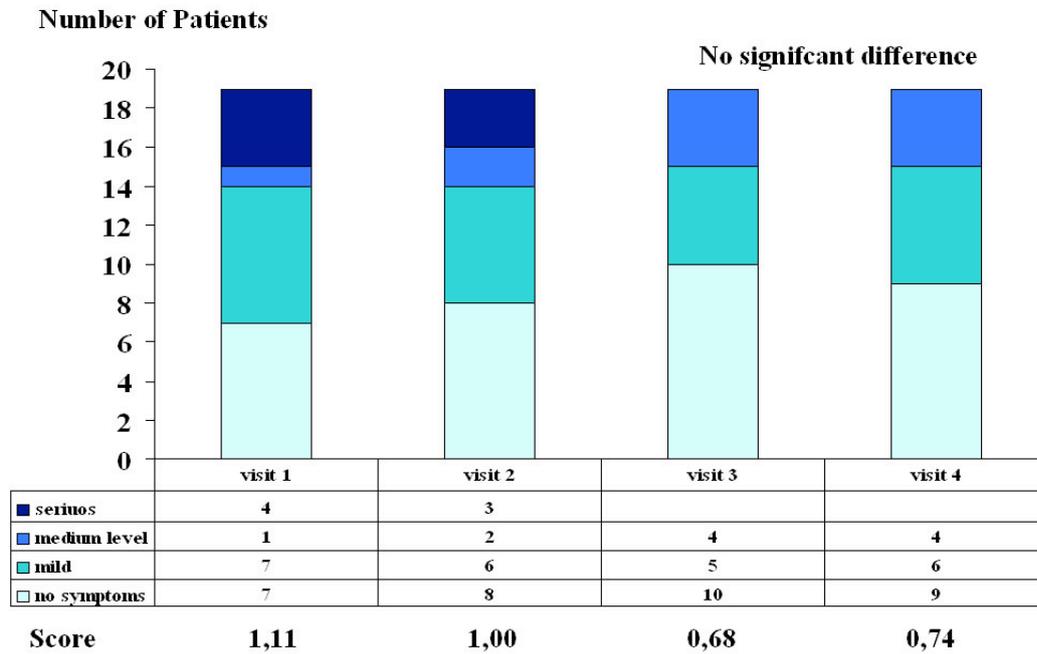


**Figure 11.:** Severity of erythema in psoriasis capitis patients as a function of PSORIT-X cream shampoo treatment

## D. Itching

As it can be seen from **Figure 12.**, the use of PSORIT-X cream shampoo has a tendency to reduce the severity of itching of the scalp in psoriasis capitis but the change in this clinical trial has not reached the level of significance.

# Symptoms of ITCHING

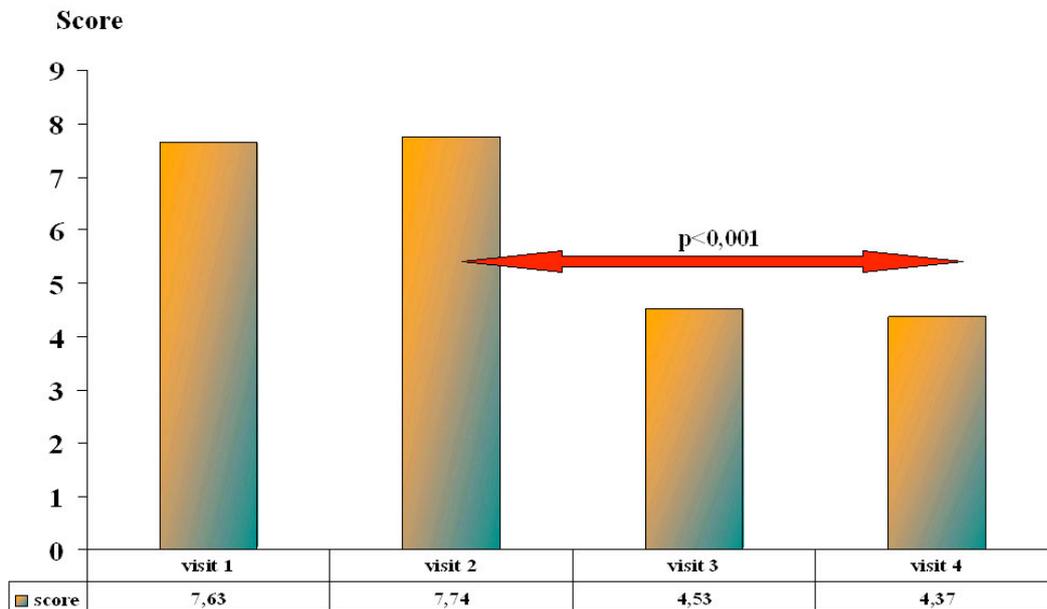


**Figure 12.:** Severity of itching in psoriasis capitis patients as a function of PSORIT-X cream shampoo treatment

## E. Summary of score of symptoms

The summary score of symptoms (see **Figure 13.**) shows that the combined scores of the examined parameters significantly decrease between visits 2 - 4.

## Summary Score of Symptoms



**Figure 13.:** Summary score of symptoms in psoriasis capitis patients

### *Cosmetic effect/tolerability*

A./ The patient's (subjective) evaluation on the efficacy of treatment (see **Figure 14**)

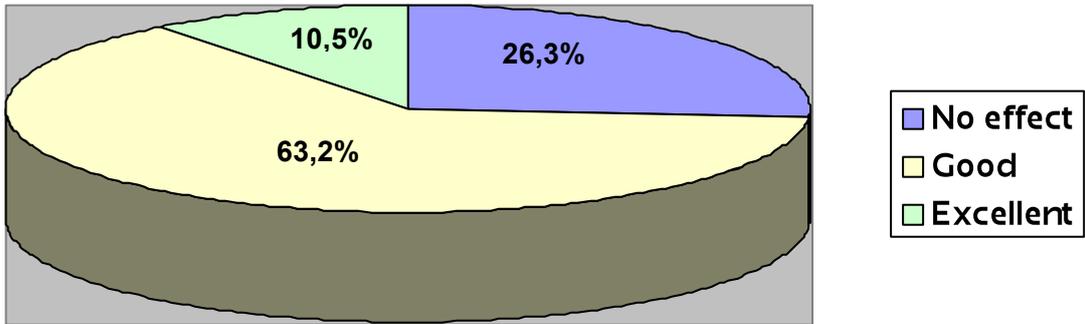
|           |              |
|-----------|--------------|
| No effect | <b>26,3%</b> |
| Good      | <b>63,2%</b> |
| Excellent | <b>10,5%</b> |

B./ The doctor's evaluation on the efficacy of treatment (see **Figure 15**)

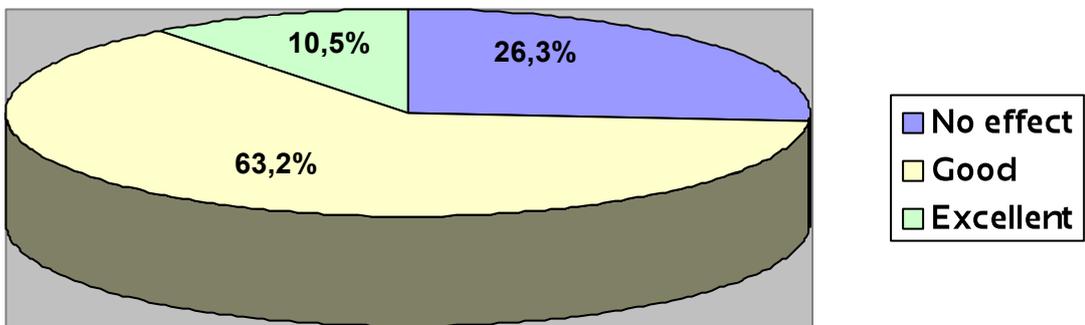
|           |              |
|-----------|--------------|
| No effect | <b>26,3%</b> |
| Good      | <b>63,2%</b> |
| Excellent | <b>10,5%</b> |

C./ Would the patient later intend to use the study preparation (see **Figure 16**)?

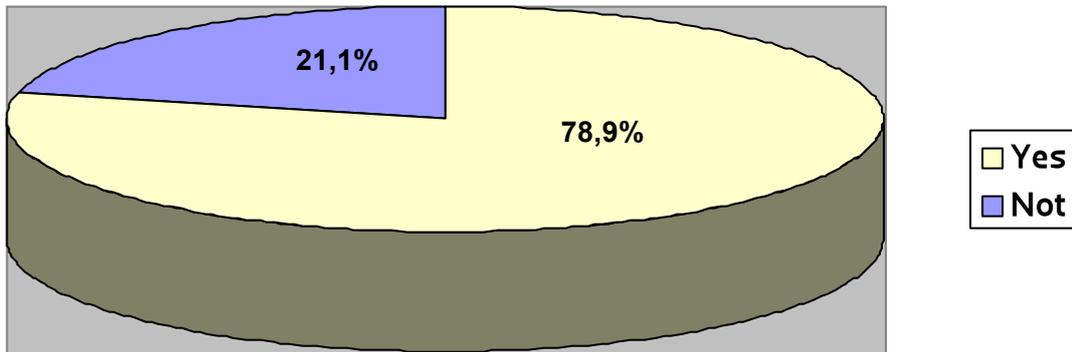
|     |              |
|-----|--------------|
| Yes | <b>78,9%</b> |
| Not | <b>21,1%</b> |



**Figure 14.:** The patient's (subjective) evaluation on the efficacy of treatment



**Figure 15.:** The doctor's evaluation on the efficacy of treatment



**Figure 16.:** Would the patient later intend to use the study preparation?

### *Possible side effects*

In one female patient itching developed (4<sup>th</sup> visit). Intensity: 2 (moderate); Connected to the use of shampoo: 3 (possibly); symptomatic treatment: 2 (not needed).

In one male patient 5 minutes after the use of the shampoo itching developed (3<sup>rd</sup> visit). Intensity: 1 (mild); Connected to the use of shampoo: 3 (possibly); symptomatic treatment: 2 (not needed).

## **Chapter 6.**

### **Discussion**

Prior to the above described open clinical study, experiences on the efficacy and safety of PSORIT-X cream shampoo has been limited to case reports from many thousands of patients who used the preparation. Their feed-back was generally very positive.

However, until now there was no *lege artis* clinical data and IN VITRO Ltd. decided to perform the above open, prospective clinical trial to prove PSORIT-X cream shampoo's efficacy and safety in seborrhoea capitis and psoriasis capitis in a dermatological clinical setting.

This trial will be continued and extended to accumulate additional long-term data.

According to the results **in seborrhoea capitis** PSORIT-X cream shampoo **significantly** reduced the severity of desquamation, inflammation, fattiness of the hair and itching which are the leading symptoms of seborrhoea disturbing very much the quality of life of the patients.

99,4% of the seborrhoea patients and the doctors found PSORIT-X cream shampoo to have excellent or good efficacy and 99,4% of the patients intended to continue the use of the preparation.

**In psoriasis capitis** parakeratosis, infiltration and erythema have been **significantly** reduced. Itching had a tendency to alleviation but the result did not reached the level of significance.

73,7% of the psoriatic patients and the doctors found PSORIT-X cream shampoo to have excellent or good efficacy and 78,9% of the patients intended to continue the use of the preparation.

**As to the safety**, in the seborrhoea capitis arm of the study one patient dropped out because of contact dermatitis-like symptoms. In the epicutan allergy test he had hypersensitivity to fragrance mix and balsam of Peru. (PSORIT-X cream shampoo contains neither added fragrances nor balsam of Peru. Allergology testing for these substances is part of the routine medical test procedure.).

In the psoriasis capitis arm in two patients itching developed at various times during the study with possible connection to the use of the cream shampoo. No special treatment was needed.

**The exact mechanism of action** of PSORIT-X cream shampoo is unknown. The active ingredients (propolis, sea salt, medicinal plant extracts and vitamins) of the cream shampoo contain compounds of antiinflammatory and antimicrobial effects and are well known and used in the treatment of inflammatory skin conditions, among others in seborrhoea and psoriasis. The original idea behind PSORIT-X was their combination in one preparation hypothesizing that they could have synergistic effects.

The clinical results support this hypothesis but the exact role of the individual components remain unknown. The highly lipophilic vehicle plays an additional, important role in the effect, partly by supplementing lipids to the scalp.

## **Chapter 7.**

### **Conclusions**

PSORIT-X cream shampoo can be successfully used

- **in seborrhoea capitis** to significantly reduce the severity of desquamation, inflammation, fattiness of the hair and itching, and
- **in psoriasis capitis** to significantly decrease parakeratosis, infiltration, and erythema. Itching can be influenced positively, too, but the cream shampoo's effect regarding this parameter does not reached the level of significance in the above open clinical trial.

The beneficial effects appear quickly, usually after one week of daily treatment.

The safety of PSORIT-X cream shampoo is good. In some cases hypersensitivity or itching can develop.

Based on the earlier case report from thousands of patients and on the results of the above open clinical trial **PSORIT-X cream shampoo can be successfully used in mild to medium level seborrhoea capitis and psoriasis capitis as a first-line therapy before other medicines of stronger effects and with a risk of serious side effects are tried.**