Pilot study to prove the effects of concomitant application of SKIN-CAP® (shampoo, spray) and administration of SKIN-CAP® capsules (both produced, modified and fortified by Cheminova Internacional S.A. Madrid) to adult patients with mild to moderate psoriasis vulgaris

Final Report

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Introduction

During the period from January 15\textsuperscript{th}, 2007 to April 15\textsuperscript{th}, 2007 a pilot study to prove the effects of concomitant application of topical SKIN CAP\textsuperscript{®} preparations including shampoo and spray and systemic administration of SKIN CAP\textsuperscript{®} capsules, all products of Cheminova Internacional S.A. Madrid, in patients with mild or moderate psoriasis forms was performed.

Compared to other products, the new range of SKIN CAP\textsuperscript{®} products including shampoo, spray and capsules were modified differently in the laboratory, and were presented now with fortified action and effects.

For the purposes of the study the said SKIN CAP \textsuperscript{®} products had been delivered to the centres by Cheminova International S.A. Madrid and applied and administered to patients in practice.
Psoriasis vulgaris, its definition and therapy

Psoriasis (psoriasis vulgaris) is one of the groups of erythematousquamous inflammatory diseases. According to latest statistical data research, it affects 2% of Central European population. Psoriasis may not be imminently life threatening; however, its influence on the everyday life of the affected individual is enormous. The quality of life of psoriatic patients is comparable to the quality of life of those patients suffering from cancer, diabetes or depression (1.16). There is a whole variety of forms and clinical pictures of psoriasis (1,4). There is classic psoriasis with lesions on the elbows, knees, on the scalp or psoriasis with single morphs spread anywhere on the area of the skin (gutatte psoriasis) or creating extensive „geographic patches“ of bizarre shapes often covering great huge areas of the trunk and of the extremities (psoriasis numularis, psoriasis geographica). What is also typical of the disease are small or quite extensive slightly protruding reddened lesions (flat papules) covered by a silvery, flaky surface. In very limited cases patients shed their skin from the plaques in form of fine dry silvery dandruff. Many patients develop psoriasis on the scalp (psoriasis capillitii) and also in this condition, dandruff appears. Moreover, psoriasis not only affects the skin, but may appear on nails (psoriasis unguium) with specific changes of the nail plate such as tiny white pits scattered in groups across the nail. In some cases the nails get deformed and may develop ridges or start separating. In general, the nails develop a yellowish or yellow-greyish colouration. In exceptional cases the disease outbreaks affect the joints (psoriasis arthropatica) – from the small joints of the fingers and toes to knee joints and other joints on the whole body. What needs to be said here is that joints are never affected symmetrically, as is the case in rheumatic diseases.

Another very serious form of psoriasis is a condition where the entire body skin surface is affected. This condition is called psoriatic erythroderma. Some patients even may develop psoriasis of the mucous membrane (psoriasis mucosae oris) and on the genitals (psoriasis inversa). One of the typical manifestations of psoriasis also is Köbner phenomenon, where patients show the practically overnight development of a psoriatic skin lesion on a site of injury or trauma such as a scratch, pressure or an operation scar. Acute psoriasis development is observed in patients suffering from stress, infections, from patients getting a cold or undergoing an operation. According to the peak time of outbreak psoriasis may be divided into psoriasis of type I, (with patients developing psoriasis in their twenties) and psoriasis of type II, with patients developing this type of psoriasis after they’ve reached the age of 40. According to the severity grade psoriasis is divided into mild, moderate and severe forms. (1, 4). Quantitative criteria are used for the purposes of clinical trials, such as the area extent given in percentage of the affected overall body area or the combined psoriasis area and severity index PASI.

The main principle of psoriasis therapy is to control the course of the disease defined as significant decrease of the extent and the intensity of the skin manifestations and the improvement of the quality of life of the patient while maintaining minimum acceptable Adverse effects (1, 4, 12). In general, there are two therapeutic approaches – one of them is
the acute intervention treatment and the other is long-term maintenance therapy. It is necessary to adopt a special and responsible approach towards every patient and pay close attention to the manifestations in every individual. The therapeutic approach is based on the clinical stage of the disease, respecting and taking into consideration the severity of the disease. Mild forms of psoriasis are treated with topical preparations. Moderate and severe forms are treated with systemic preparations and phototherapy, with topical therapy being of adjuvant importance. (1, 4, 12, 13).

To treat psoriasis is very difficult and money consuming (1, 4, 13, 16). While choosing the treatment all specific individual factors must be taken into consideration, which, in the long run, may be decisive for the positive perception of the therapy by the patient (4). If the therapist chooses to select a specific therapeutic approach, it is necessary to take into consideration its relative and absolute contraindication, (both short-term and long-term) safety, drug interactions, possibility of therapeutic combinations, availability and price as well as the willingness of the patient to undergo the possible risk of adverse effects.

The basics of psoriasis treatment are ointments, creams, pastes, solutions and bath products (1,10,13). The main advantage of **topical preparations** is their targeted application, high safety and relatively low price. The therapeutic potential is their targeted application, high safety and relatively low price. The therapeutic potential may be assessed in every patient based on the analysis of anamnesis and previous therapy success.

The pillars of **topical therapy** include (1, 12, 13):

- Topical corticosteroids
- Vitamin D analogues – Calcipotriol
- selective retinoids – Tazarotene
- Ditranol (Cignoline, Antraline)
- coal tar
- Ichthamol, salicylic acid (3-5%)
- urea
- electroforetically modified and activated Zinc pyrithionate (2, 17,18)
- emollients
- phototherapy
- photochemotherapy (PUVA)
- UVB phototherapy in the upper range of 311 nm (UVB 311)
- TOMESA - a treatment method combining UV irradiation of the whole body immersed in water with added sea salt.

**Systemic therapy** is to be employed in patients with moderate and severe forms of psoriasis or in those patients not responding to topical therapy and showing no signs of the disease being under control. Some systemic agents show high efficacy in some special forms of psoriasis (eythroderma, pustulous and arthropatic psoriasis). The therapist may take advantage of the following agents:

- cyclosporine A (first agent with selective immunosuppressive effect)
- metotrexate (used in an expressly empirical way)
- acitretine (vitamin A second generation analogue)
- biologics (highly molecular proteins or polypeptides produced by gene engineering having highly specific influence on the course of patophysiological reaction mechanisms in the organism) – monoclonal antibodies, fusion proteins and recombined cytokines (4)

Of course, what is necessary and also requested in many cases is the combination of systemic and topical therapy, which is possible, with the topical treatment being of adjuvant nature.

What also has proven to be an alternative (and often surprisingly effective) form of adjuvant therapy in many patients is the administration of systemic antioxidants (3), molasses extract or products of traditional medicine, vitamins and minerals.

Lately, many patients showed interest in nutrition supplements that exhibit very good results in combination with topical therapy of mild and moderate psoriasis and, what is of great advantage, prolong the period of remission and improve the quality of life especially when employed systemically. These preparations produce minimum side effects. In the past 5 years many works of great value have been published compiled by scientific teams at clinics in Russia, Latvia, Uzbekistan, Azerbaijan, Romania, South Africa and other countries with reported excellent results obtained while employing the preparation VIUSID® (Catalysis, S.L., Madrid) in experiments (7). HIV therapy and the therapy of various virus diseases as well as a variety of skin diseases (especially psoriasis in children as well as in adult patients) (5, 6, 8, 9, 11, 14, 15, 18). The company Cheminova Internacional S.A. Madrid has
successfully introduced to the market a new product to treat psoriatic patients, namely SKIN CAP® capsules (19).

Product composition and characteristics:

**SKIN-CAP®, Cheminova Internacional S.A. Madrid, cream, spray, hair shampoo and capsules.**

The first written records of the possibility to take advantage of the properties of Zinc pyrithionate as an effective therapeutic agent to treat patients with papulosquamous skin diseases and eczema trace back to 1965. Later on, there were many serious works of science produced by dermatologists, pharmacologists and laboratory staff that have verified and proven the proclaimed effects of the preparations in practice.

Zinc pyrithionate is used as the active substance in products manufactured by many companies within their production programme. The companies take advantage of this substance on its own or employ it in combination with Liquor Carbonis Detergens. The production of Zinc pyrithionate containing products was launched also by the Spanish company Laboratorios Cheminova Internacional, S.A. more than 20 years ago. The products created were named SKI-CAP® and the original formulation of a shampoo was later extended by the formulation of spray, cream, tablets and **bath foam**. The company really is interested in serious assessment of their products, which is why it commenced numerous extensive multicentre clinical studies carried out in different geographic zones - the tropical and the temperate zones, as well the regions of Siberia.

The active substance of SKIN-CAP® is Zinc pyrithionate, (zinc-2-pirydinethiol-1-oxid) and its molecule has been (unlike in other modern commercial products containing this active agent) electroforetically modified, which is why it has a different structure. In combination with other active substances (such as isopropyl-myristat, methyl ethyl sulphate, Sorbitol and other substances) it was possible to create products with excellent properties. Zinc pyrithionate demonstrates a verifiable antiseptic, antimicrobial, antimycotic, and keratolytic effect.

The effect is selective, affecting only the cells modifies due to the disease. Zinc pyrithionate concentrations used in SKIN-CAP® preparations are absolutely safe. The preparations may be used on extensive body areas by practically all age categories.
The dosing of SKIN-CAP® capsules is as follows: adults ought to be administered 2 capsules 3 times a day before a meal. Children over 6 years of age ought to be administered 1 capsule 3 times a day before a meal. It is advisable to continue taking in the capsules until resolution of the symptoms occurs and no manifestations are visible on the skin. Thus the time of administration is dependent on the severity and form of the disease

Conclusion: Zinc pyrithionate shows many positive effects on the pathological processes present in the skin, such as the significant antimicrobial and antifungal effect or the selective cytostatic effect on the skin cells (in their hyperproliferation stage, only, leaving the healthy cells uninfluenced), it regulates the number of cell enzymes and determines the anti-inflammatory effect (if employed selectively in topically applied preparations).

Study objective:

To prove the efficacy and tolerability of the preparation SKIN-CAP® (shampoo, spray) applied concomitantly with the administration of SKIN-CAP® capsules produced, modified differently and fortified by Cheminova Internacional Madrid and to prove the differences in tolerability, efficacy and effect onset acceleration in individual adult patients with psoriasis vulgaris and to prove that there are differences in healing acceleration in those patients administered the capsules.

In order for us to be able to assess the effects and especially the acceleration of its onset, patients were chosen who have already had experience with topical SKIN-CAP® preparation application in the past with good results.

Study design:

30 adolescent and adult patients with mild and moderate psoriasis vulgaris aged 14 to 65 years (of comparable age, sex, and disease extent) were applied topical SKIN-CAP® preparations including spray and shampoo and administered SKIN-CAP® capsules (Cheminova Internacional S.A., Madrid).

Study type:
International, prospective, randomized, controlled multicentre study of type IV; with post-registration monitoring and continuous inclusion of patients into the study according to set criteria and age.

**Time schedule:**

- December 2006 - patient inclusion and exclusion
  - January 15\(^{th}\), 2007 - April 15\(^{th}\), 2007 study performance
  - April 15\(^{th}\), April 30\(^{th}\), 2007 – assessment and processing of results
  - April 2007 – handing over of a complete results assessment
  - April - December 2007 – presentation and publication of results

**Materials and Methods**

The clinic carrying out the study agreed that they would elaborate the documentation, take pictures, and inform the ordering party about any conditions in connection with the performance of the study.

The clinic worked with and according to the following **basic set of documents:**

- Basic working protocol (Annex 1)
- Inclusion and exclusion criteria (Annex 2)
- Working and assessment table (Annex 3)
- Total number of patients (Annex 4)
- Patient consent form (Annex 5)

**Clinic:**
DOST Svidník

**Study duration:**
January 15\(^{th}\), 2007 – April 15\(^{th}\), 2007

**Group of patients:**
30 patients (16 male, 14 female)

**Average age:**
33.9 years (39.5 years in female and 30.7 years in male patients)

The youngest patient was a female aged 14
**Diagnosis:** mild and moderate forms of psoriasis vulgaris, affecting up to 40% of total body surface

* **Disease duration:** 10.5 years on the average (9 years in women, 12 years in men)

All patients relapsed.

* **Present episode duration (exacerbation)** 6.5 months (5 in men, 8 in women)

* **Number of relapses in a year:** 2 in men, 3 in women

**Extent** The extent of affected skin and scalp varied from 10 – to 40% of total body surface.

**Local finding assessment:** performed 3 times – at inclusion onto the trial and after 4 and 8 weeks.

Local finding assessment was performed according to clinical picture.

**Inclusion criteria:**

- Moderate and severe psoriasis vulgaris
- Disease duration of minimum 3 months
- Male or female sex, Caucasian
- Resistance to previous therapy
- Inpatient or outpatient status
- Age of more than 12 years
- Voluntary participation in the study
- Written patient consent form confirmation
- One-time participation in the trial
- Other (such as frequent relapses)

**Exclusion criteria:**

**Specific exclusion criteria**

- Patients with untreated Diabetes mellitus
- Change in hormonal therapy within the past three months
- Known allergies to the tested preparation
- Disease focus infection manifestations (therapy requiring superinfection)
- Immunosuppressive therapy
- Cancer
- Malignancies
- Employment of other drug/s and/or preparation/s in therapy

**General exclusion criteria:**
- Alcohol and drug abuse
- Painkiller abuse
- Pregnancy or lactation in female participants
- Participation in another clinical trial within the past 30 days
- Simultaneous participation in any other clinical trial
- Other reasons excluding the patient from the trial
- Restricted ability of the patient to follow therapy instructions
- Other physical or mental disorders disturbing the trial plan
- Possible consent withdrawal, presumed patient unreliability

**Preparation employed:** SKIN-CAP® spray, shampoo, Cheminova Internacional Madrid
SKIN-CAP® capsules, Cheminova Internacional Madrid

**Composition:** SKIN-CAP® spray, shampoo, Cheminova Internacional Madrid

*see producer standard + modification information*

SKIN-CAP® capsules, Cheminova Internacional Madrid

Activated Green Tea Extract, Arginine, Glycine, Fumaric Acid, Ascorbic Acid, L-Carnitine, L-Cysteine, Ornithine, Acetylcysteine, Pyridoxal, Folic Acid, Cyanocobalamin, Zinc Sulfate and Calcium Pantothenate, Fumaric Acid, zinc sulphate and blueberry antioxidants
Number of applications:  
spray  2 times a day spray,

  shampoo  1 time a day or according to condition

SKIN-CAP® administration regimen:  
adults: 2 capsules 3 times a day before a meal

*Administration and application period:* of systemic and topical preparations comprised 60 days.

*Note:*  
10 patients were taking 2 SKIN-CAP® capsules 3 times a day during 60 days,
20 patients were taking 2 SKIN-CAP® capsules 3 times a day during 30 days
and 1 capsule 3 times a day during the following 30 days

Concomitant application or administration of other preparations:
In emergency cases exclusively and based solely on recommendation of other medical experts

Patient information:  
provided by the therapist regarding both topical application and systemic administration. All patients have been informed about possible adverse effects.

Laboratory screening:  
performed 2 times before therapy commencement and upon therapy termination

Special examinations:  
Focal infection examination performed in all patients – the results obtained are not subject of this study

Documentation:  
work protocol

Photodocumentation:  
pictures taken during regular check-ups

Recommended daily hygiene:  
non irritating preparations having no influence on study course

Therapy effect assessment made by the therapists and the patients:

(1- very good, 2 – good,
3 – without effect, 4 – aggravation, 5 – no tolerability).

Therapy tolerability assessment made by the therapists and the patients:

(1- excellent, 2 – very good, 3 – good,
4 – without changes, 5 – no tolerability)
Comment: The differing application and administration periods of topical as well as systemic SKIN-CAP® preparations were conditioned by the extent of the areas to be treated as well as the volumes of the said preparations delivered by the company.

Note: the data marked with * are to be found in Table No. 1, and Graphs No. 1 and 2

The figures in columns indicate the numbers of patients.
**Basic data:** For gender, number of patients, age (lowest, highest), average application
duration period (in days), average disease duration period (in years), average exacerbation
period duration and number of relapses per year see **Table No.1, and Graphs No.1 and 2.**

**Specialised data:** For application discontinuation, hospitalization, and most effective
preparations see **Table No. 2 and Graph No. 3.**

**Specific data:** For efficacy and tolerability, assessments made by the therapist and the patient,
and for adverse effects see **Table No. 3, and Graphs No. 4 to 9.**

**Comment:** In the group of 30 patients (consisting of 16 men and 14 women), mild and
moderate psoriasis forms (evaluated according to PASI) affecting up to 40% of total body
surface (trunk, extremities, scalp) were treated.

There also were some patients suffering from occasional joint pain, and some patients with
affected nails. Some patients suffered from inverted psoriasis

**Previous therapy:** a number of topical preparations (salicylates, corticoids), systemic
PUVA, cyclosporine A, Balneotherapy, and retinoids

**Note:** *All patients have been treated with topical SKIN-CAP® (Cheminova
International S.A., Madrid) preparations in the past.*

**Positive family anamnesis:** detected in 7 patients (23.33%)

**Laboratory screening:** 3 cases of elevated cholesterol level,
4 patients with liver tests on the verge of normal values,
1 case of glycaemia on the verge of normal range

**Other medication:** vitamins, reborans, antihistaminic agents

Other medication was employed in emergency cases exclusively and based solely on
recommendation of other medical experts.

**Local finding improvement** was observed already within the first 2 weeks and continued until
the termination of both the application and administration of the tested preparations.

**Remission period duration:** impossible to assess so far

**Therapy efficacy (see Table No. 3, and Graphs No. 5, 7, and 9):**
Assessment made by the therapist: 17 (56.67%) patients – very good, 8 (26.67%) patients –
good, 5 (16,67%) patients – without effect.
Assessment made by the patients: 18 (60%) patients – very good, 9 (30%) patients – good, 3 (10%) patients – without effect

*THERAPY TOLERABILITY (see Table No. 3, and Graphs No. 6, 8, and 9)*

Assessment made by the therapist: 19 (63.33%) patients - excellent, 10 (33.33%) patients - very good, 1 (3.33%) patients - good

Assessment made by the patients: in full compliance with the assessment above

*LOCAL FINDING IMPROVEMENT* by 25-50% was observed already after 2-3 weeks and continued until the termination of both the application and administration of the tested preparations, reducing disease manifestations by 70%.

**SKIN-CAP® TOLERABILITY** was very good and good

**UNDESIRED EFFECTS OF SKIN-CAP® SPRAY** (see Table No. 3, Graph No. 4):

1 patient (3.33%) skin burning sensation
1 patient (3.33%) short term skin dryness
2 patients (6.67%) skin reddening
2 patients (6.67%) itching

None of the patients discontinued application.

**SKIN-CAP® CAPSULES TOLERABILITY:** very good,

**ADVERSE EFFECTS:** no adverse effects were recorded

All patients have experienced significant improvement of their overall health condition and manifest acceleration of healing as well as significant reduction in disease symptoms.

**MOST EFFECTIVE THERAPY (Table No. 2, Graph No. 3)**

SKIN-CAP® spray (applied to scalp) in men
SKIN-CAP® capsules in women

**PATIENTS EXCLUDED FROM THE GROUP:** none

**HOSPITALISED PATIENTS:** none
For direct comparison of efficacy and tolerability see Table No. 3 and Graphs No. 5 to 9

Therapy efficacy by the therapist:
(see Table No. 3, and Graphs No. 5, 7, 9)
17 patients (56.67%) – very good
8 patients (26.67%) – good
5 patients (16.67%) - without effect

Therapy efficacy by the patients:
(see Table No. 3 and Graphs No. 6, 8, 9)
18 patients (60.00%) – very good
9 patients (30.00%) – good
3 patients (10.00%) - without effect

Therapy tolerability by the therapist:
(see Table No. 3 and Graphs No. 5, 7, 9)
19 patients (63.33%) – excellent
10 patients (33.33%) – very good
1 patient (3.33%) – good

Therapy tolerability by the patients:
(see Table No. 3 and Graphs No. 6, 8, 9)
19 patients (63.33%) – excellent
10 patients (33.33%) – very good
1 patient (3.33%) – good

| Therapy efficacy as assessed by the therapist was very good and good in 25 patients | Therapy efficacy as assessed by the patients was very good and good in 27 patients |
| (out of the group of 30 patients) | (out of the group of 30 patients) |
| 83.34% | 90% |

| Therapy tolerability as assessed by the therapist was excellent and very good in 29 patients | Therapy tolerability as assessed by the patients was excellent and very good in 29 patients |
| (out of the group of 30 patients) | (out of the group of 30 patients) |
| 96.66% | 96.66% |

Discussion
The submitted report summarises the results of a three-months pilot study to prove the effects of concomitant application of SKIN-CAP® preparations (shampoo, spray) and the administration of SKIN-CAP® capsules (Cheminova Internacional S.A., Madrid). All products have been modified and their effects fortified by the producer, as compared to other competing products on the market.

Local effects of SKIN-CAP® products (spray, shampoo, cream, bath and shower gel) in patients with various types of psoriasis are well known and have been proven by numerous studies performed at renowned clinics.

SKIN-CAP® capsules produced by Cheminova Internacional Madrid are marketed as an extraordinary new generation nutrient, whereby all components are activated and their biologic activity is increased. As has been pointed out above, the capsules have been specially modified and their effects fortified.

SKIN-CAP® capsules are composed of antioxidants – vitamins, minerals, amino acids and plant extracts. The indication group includes patients suffering from psoriasis, seborrheic dermatitis, atopic eczema and other eczema forms. The application of the said products accelerates wound healing and skin regeneration, reduces the manifestations of the disease, prolongs remission periods and prevents relapses. SKIN-CAP® capsules represent an excellent supplement to SKIN-CAP® dermatocosmetics. Their active ingredients include green tea extracts (stimulating collagen remodelling by strengthening its structure and improving skin texture), Arginine (improving immunity, supporting tissue repair and synthesis of collagen in the skin), Glycine (positively influencing thy synthesis of nucleic acids), Fumaric Acid, Vitamin C, L-carnitine (active in fat metabolism), Ornithine (improving brain cells metabolism), L-cysteín (improving the quality of skin), Calcium Pantotenate, Vitamin B6, Folic Acid (important biocatalyst), Vitamin B12, green lettuce extract (decreasing blood sugar level by up to 30%). Green tea extract, zinc sulphate and blueberry antioxidants.

According to the laboratory and clinical tasting performed, the preparations may also be employed in pregnant and lactating women and in children.

While elaborating the results we came to the conclusion that it is necessary to pay attention to proper indication and select patients carefully. Patients suffering from mild and moderate psoriasis types with previous experience with topical application of SKIN-CAP® products were chosen to participate in the study, and we therefore consider the
results obtained of great relevance. There is no doubt that the modified and fortified SKIN-CAP® capsules are a high-quality product manifestly accelerating healing in patients with mild and moderate psoriasis forms.

It is necessary to consider selecting a group of patients suffering from severe psoriasis forms and observe them separately.

It is inevitable that in the future combined therapy consisting of topical application of topical SKIN-CAP® products and systemic administration of SKIN-CAP® capsules is employed taking into consideration the overall condition of the patient, any accompanying diseases they might be suffering from as well as their mental state and the season in which the therapy is commenced.

_The time that had passed from the termination of the study until the elaboration of the report was too short to asses the dynamics of the disease course and to presume the time of possible relapses was too short. It is therefore advisable to consider a catamnestic observation for instance a year after the termination of the study._

It is also advisable to consider the performance of a pilot study to prove the effects of the therapy in question (SKIN-CAP® capsules by Cheminova Internacional S.A., Madrid) also in patients undergoing a combined psoriasis therapy with cyclosporine and retinoids. There is a premise that SKIN-CAP® capsules could improve the overall health condition of the patients and accelerate the process of healing.

For patients, in which topically applied preparations don’t seem to be really efficient, in which it is impossible to employ systemic therapy with other agents (cyclosporine A, retinoids, biologics) due to various reasons, and in elderly or immunodeficient patients the topical application of SKIN-CAP® products accompanied by administration of a high-quality systemic preparation with significant effects, namely SKIN-CAP® capsules (Cheminova Internacional S.A., Madrid) represents an elegant therapeutic approach and a method to improve their local finding as well as their overall condition, resulting in a significantly better quality of life.
Conclusion

The report describes the results of a three month’s observation of patients with mild and moderate psoriasis (affecting from 10 to 40% of total body surface) that were using topical preparations of the SKIN-CAP® range (shampoo, spray) and SKIN-CAP® capsules, all modified differently compared with other preparations.

Great effects were observed in 5 patients after 14 days of therapy. Those patients also reported that they physical condition had improved significantly. In other patients the improvement started within 20 observation days on the average and continued until study termination. Scaling, erythema and infiltration were eliminated quickly. Even after the trial had been terminated, the patients asked both for the topical and systemic preparations.

No changes of the local finding were reported very sporadically and so were the undesired effects following the topical application (SKIN-CAP® spray). Apart from the positive assessment made by the therapist, the patients reported that they had very much appreciated the effects of all preparations, namely the fact that they accelerated the resolution of their symptoms compared to other competing topical products they would use in the past.

The assessment of therapy efficacy made by the patients stated below is surprisingly positive.

| Therapy efficacy as assessed by the therapist was very good and good in 25 patients (out of the group of 30 patients) | 83.34% |
| Therapy efficacy as assessed by the patients was very good and good in 27 patients (out of the group of 30 patients) | 90% |

What needs to be stated here is the important observation that in this group of patients, the results were not influenced by negative mental states, stress or adjuvant infectious diseases (influenza infection, tonsillitis, upper respiratory tract infection).
Despite the short observation period and small group of patients we may state that the declared molecular activation seems to be of great advantage as regards the final efficacy of the product range. There is no doubt that the patients should be treated with the combination of topical and systemic SKIN-CAP® products (Cheminova Internacional S.A. Madrid).

Because it was not possible to assess remissions and relapses, we recommend a group of patients be observed after six months or a year within an extensive international multicentre study.
Bibliography:

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