PSORIASIS.

Clinical trials carried out with an aerosol based in Zinc Pyrithione 0.2%.

Prof. Luis Carlos Pereira and Dr. Sergio Fonseca Tarlé (Chair of Dermatology of P.U.C.-Curitiba/Pr.), and collaborators. Irmandade Santa Casa de Misericórdia- Curitiba/Pr (July 97).

SUMMARY.

The Dermatological Service of the "Irmandade da Santa Casa de Misericórdia" in Curitiba, has performed an open clinical trial with 20 patients of both sexes who showed a diagnosis of psoriasis.

The mentioned trial was carried out with a cosmetic in launching process in Brazil, commercial named BLUE-CAP SPRAY. The pharmaceutical form of this product consists of an aerosol solution of topical use based in Zinc Pyrithione 0.2%.

INTRODUCTION.

In clinical trials with patients of psoriasis, high incidence dermatitis and outstanding chronicity, the medicaments currently available for the medical class are not completely effective neither for the stop of the disease nor for the treatment of recurrence of it. These medicaments, are topical or systemic ones. The systemic medicaments have a higher effectiveness, but also serious colateral effects may occur.

Concerning to drugs of topical use, the available bibliography stands that the association of a molecule of Pyrithione with a tensoactive agent is particularly effective against psoriasis,
justifying the basis for this clinical trial: Find and demonstrate that this new pharmaceutical aerosol means an efficacious and secure advance in the treatment of the different types of psoriasis (basically the common type).

MATERIALS AND METHOD.

A clinical trial was carried out with 20 patients of both sexes and ages ranged from 11 to 75 years old. The study was performed during their periodical visits to ambulatory for the treatment of psoriasis.

The exclusion criteria were established as follows:

- Pregnant women or women who develop amenorrhea for more than 4 days.
- Women during the period of lactation.
- Patients suffering from mental, hepatic or renal severe diseases.
- Patients suffering Psoriasis as well as other dermatological diseases which may modify the evolution of their psoriasis.
- Patients following a systemic treatment with corticosteroids or another anti-psoriasis medicaments.
- Patients not able to interrupt any sort of topical medication during the week before to the beginning of the study.
- Patients receiving through systemic route drugs which have a potential capacity to worsen the psoriatric processes, such as: Betablockers, synthesis antimalarial drugs or non steroidal anti-inflammatory in high dose (equivalent to 1 g of Acetil Salicylic Acid) per day.
- Patients incapable of understanding properly the conditions established in the clinical trial.

DIVISION ATTENDING TO AGE AND SEX.

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<table>
<thead>
<tr>
<th>AGES</th>
<th>11-20</th>
<th>21-30</th>
<th>31-40</th>
<th>41-50</th>
<th>51-60</th>
<th>61-70</th>
<th>&gt;71</th>
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</thead>
<tbody>
<tr>
<td><strong>MEN</strong></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>2</td>
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<tr>
<td><strong>WOMEN</strong></td>
<td>1</td>
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**METHODOLOGY.**

1.- **Duration of the study.**

The duration of the treatment was about 4 weeks (28 days) and it consisted in semanal visits to ambulatories, where patients were controlled.

2.- **Dosage.**

The dose used in the study consisted in two daily nebulizations: In the morning and in the evening. The product is sprayed over the affected area, by means of a dosifier valve. The application lasts 2 seconds, covering about 0.6 cm of skin surface with the tested solution.

3.- **Validation of results.**

A previous valuation (First visit-Day 0), was effected in every patient in order to verify the possibility of the patient to suffer contact allergies, or another concomitant diseases and the kind of medication used against them. All this let to have an efficient control of the medication, setting up an opportune identification of whatever eventual deviation from the established standards. The strictness of lesions was classified according to its intensity:

( Slight-1 / Moderate-2 / Intense-3 / Very intense-4 ).

It was classified as well according to the time:
- Registered before treatment (Visit 1-Day 0).
- During treatment (Visit 2-Day 7 / Visit 3-Day 14 / Visit 4-Day 21 and final visit 5-Day 28).

During visits 2, 3, and 4, it was also valuated:

- Appearance of eventual colateral effects.
- Changes in the status of concomitant ailments.
- Possible changes in concomitant medications since the last
visit.
• Interruption of the treatment because of the following reasons:
  - Inadequate action.
  - Intolerance.
  - Patient not coming to controls.
  - Patient who interrupted unilaterally the treatment.
  - Other reasons (specify which ones).

4.- Global effectiveness.

The results of the observation were summarized in the following table:

<table>
<thead>
<tr>
<th>Clinical forms</th>
<th>Total number of cases</th>
<th>Final Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plaques</td>
<td>15</td>
<td>7</td>
</tr>
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<td></td>
<td></td>
<td>4</td>
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<td>4</td>
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<td>Generalized</td>
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<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Percentages</td>
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<td></td>
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<td></td>
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<td>25%</td>
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</table>

It is important to emphasize the high value reached by the cosmetic acceptability of the product, mainly for those who have located the process in the scalp.

With relation to the general tolerance, it was also observed a highly satisfactory level, without any case which justified the suspension of the treatment or an alteration in the dosage.

About a 15% of the patients reported to have felt a sensation of slight itching, which finally disappeared within 3 or 4 visits.

It was also detected one case of grooves in the second visit which retreated substantially at the end of the treatment.

5.- Average number of sprays used for the treatment per person.

In the present study, the average of cans used per patient was 6 cans.

6.- Final remarks.
According to the performed observations, the product BLUE-CAP is capable to constitute an efficient therapeutical arm for the control of psoriasis, thanks to its good tolerance, its almost absence of colateral effects and its optimum results, that can be already observed at the first applications.

The application of the product over the surface of the affected area, can be done in an extremely convenient way and it is cosmetically well accepted by the patients.

Note: Translated by Catalysis, S.L. Technical Department.