Clinical Study Synopsis

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# Clinical Trial Results Synopsis

## Study Design Description

<table>
<thead>
<tr>
<th>Study Sponsor</th>
<th>Bayer Healthcare AG</th>
</tr>
</thead>
</table>
| Study Number           | 0220  
NCT00000000                                           |
| Study Phase            | N/A                                                     |
| Official Study Title   | Open label, mycologically controlled study to test the efficacy (clinical and mycological) and tolerance of BAY B 5097 spray in subjects with dermatomycoses |
| Therapeutic Area       | Dermatology                                             |

### Test Product

<table>
<thead>
<tr>
<th>Name of Test Product</th>
<th>Canesten (Clotrimazole, BAYB5097)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Active Ingredient</td>
<td>bis-phenyl-(2-chlorophenyl)-1-imidazolyl-methane (Clotrimazole)</td>
</tr>
<tr>
<td>Dose and Mode of Administration</td>
<td>1% solution (W/V) sprayed twice daily, thinly and evenly over the diseased skin, for 1 to 3 seconds, depending on the extent of the skin lesions.</td>
</tr>
</tbody>
</table>

### Reference Therapy/Placebo

<table>
<thead>
<tr>
<th>Reference Therapy</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose and Mode of Administration</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

### Duration of Treatment

The duration of treatment varied according to the indication. Therapy was carried out for 3 to 5 weeks in dermatophytosis and candidiasis of the skin; for 3 weeks in pityriasis versicolor. The trial was continued until the mycological control of all patients whenever possible.

### Studied period

- Date of first subjects’ first visit: 17-Oct-1974
- Date of last subjects’ last visit: 07-Apr-1976

### Study Center(s)

The study was conducted at a single site in Germany.

### Methodology

This was an open label mycologically controlled study to test the efficacy (clinical and mycological) and local tolerance of BAY B 5097 spray in different dermatomycoses. The subjects fulfilling the inclusion criteria were enrolled independent of their age, sex and race. Sampling of material and its mycological examination (microscopic and culture) was carried out prior to the start of therapy and 2 to 3 days following discontinuation of the test drug application.

The evaluation of the therapy was done by correlating the clinical and the mycological findings after the end of the trial. The material for mycological examination was sampled every time from the same site. No cultural diagnosis was attempted for the pathogens of Pityriasis and Erythrasma. The local tolerance to the drug was also evaluated.
### Indication/Main Inclusion Criteria:

**Indications:**
- Dermatomycoses due to dermatophytes
- Dermatomycoses due to Candida species
- Pityriasis versicolor

**Inclusion Criteria:**
- Positive mycological finding by direct microscopy
- Confirmation of microscopic findings by culture and identification of pathogens
- Positive clinical findings

### Study Objectives:

**Overall:**
The aim of the study was to test the efficacy (clinical and mycological) and the local tolerance of BAY B 5097 spray in dermatomycoses

**Primary:**
To test the efficacy of BAY B 5097 spray (clinical and mycological).

To test the local tolerance of BAY B 5097 spray.

### Evaluation Criteria:

**Efficacy (Primary):**
The investigating physician correlated the clinical and the mycological findings after the end of the trial. Classification was carried out according to the following parameters:

- "Very good": Clinical and mycological cure (KOH and culture negative)
- "Good": Clinical improvement and mycological cure or clinical cure but mycologically positive
- "Moderate": Clinical improvement but no mycological cure
- "Poor": No change, neither clinical not mycological

**Safety:**
Tolerance to the test drug.
Premature cessation of therapy.

### Statistical Methods:

**Efficacy (Primary) - if applicable:**
The qualitative data relating to the diagnosis, mycological findings and therapeutic results were expressed in terms of percent rates and in cross-over tables

**Safety:**
Statistical analysis of safety was not planned.

### Number of Subjects:

At least 50 evaluable subjects were planned.
A total of 141 subjects were entered into the study; 138 were included in the final evaluation.

### Study Results

**Results Summary — Subject Disposition and Baseline**
Out of a total of 141 study subjects, 138 were included in the final evaluation. Three subjects stopped taking the drug prematurely and were excluded from evaluation.
Age of the subjects ranged from 8 to 80 years, with an average of 41 years; 104 (75%) were male, 34 (25%) were female.
Tinea pedis was the most frequent indication in 54 subjects (30.1%), followed by pityriasis versicolor in 27 subjects (19.6%), erythrasma in 23 subjects (16.7%) and tinea inguinalis in 19 subjects (13.8%).

**Results Summary — Efficacy**

The average duration of therapy was 27.7 ± 9.6 days. The shortest duration of therapy was required in pityriasis versicolor. The mycological results, both of direct microscopic examination and of culture, were negative for 59 subjects (43%). The direct microscopic findings (no culture test) were negative for 40 subjects (29%). Therefore, a total of 99 subjects (72%) were mycologically cleared. Of 129 dermatomycoses confirmed cases before treatment, 99 (77%) were mycologically cleared after 4 weeks.

According to the definition laid down in the test protocol, "cure" was achieved in 98 subjects (72%) and "improvement" in 30 subjects (22 %), giving a total therapeutic success rate of 93%. Cases of pityriasis versicolor showed an 89% rate of cure.

**Results Summary — Safety**

Three subjects (2%) reported transient local irritation. Treatment was withdrawn in 4 cases, in 2 of these 4 due to local irritation.

**Conclusion**

Therapeutic success was achieved in the tested indications, with an average treatment period of 27.7 ± 9.6 days. The test drug was locally tolerated.