Clinical Study Synopsis

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The study listed may include approved and non-approved formulations or treatment regimens. Data may differ from published or presented data and are a reflection of the limited information provided here. The results from a single trial need to be considered in the context of the totality of the available clinical research results for a drug. The results from a single study may not reflect the overall results for a drug.

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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>
<tbody>
<tr>
<td>Study Number:</td>
<td>0345</td>
</tr>
<tr>
<td>Study Phase:</td>
<td>N/A</td>
</tr>
<tr>
<td>Official Study Title:</td>
<td>Open label, mycologically controlled study of BAY B 5057 Solution N to test the efficacy and tolerability in subjects with dermatomycoses</td>
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<tr>
<td>Therapeutic Area:</td>
<td>Dermatology</td>
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</tbody>
</table>

#### Test Product

<table>
<thead>
<tr>
<th>Name of Test Product:</th>
<th>Canesten (Clotrimazole, BAYB5097)</th>
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</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>Topical application twice daily, thinly and evenly to the affected skin sites.</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:

| Duration of Treatment: | Duration of therapy depended on the mycological findings. Dermatophytoses and candidiasis of the skin: 3 to 4 weeks Pityriasis versicolor: 3 weeks When possible, the trial was run until a mycological cure was achieved in all subjects. |

#### Studied period:

| Date of first subjects’ first visit: | 08 Mar 1975 |
| Date of last subjects’ last visit:   | 08 Jun 1976 |

#### Study Center:

The study was conducted at a single site in Germany.

#### Methodology:

This was an open label, mycologically controlled study of Clotrimazole (BAY B 5097) to test the activity (clinical and mycological) and tolerance in subjects with dermatomycoses. The subjects fulfilling the inclusion criteria were enrolled independent of their age, sex, and race.

Removal of material and mycological study was done prior to commencement of treatment (with the exception of Malassezia furfur). A mycological follow-up examination was carried out at the end of the treatment, 2 to 3 days after discontinuation. Attempts were made to prepare a culture for follow-up examination. Removal of material for mycological purposes was from the same site as the first specimen.
| Indication/ Main Inclusion Criteria: | Indications:  
• Dermatomycoses caused by dermatophytes  
• Dermatomycoses caused by candida species  
• Pityriasis versicolor  
Inclusion Criteria:  
• Positive mycological findings by direct microscopy  
• Confirmation of microscopic findings by culture and identification of pathogens (for dermatophytes and yeasts only)  
• Positive clinical findings |
| Study Objectives: | **Overall:**  
The aim of the study was to test the efficacy (clinical and mycological) and local tolerance of Clotrimazole (BAY B 5097) in dermatomycoses.  
**Primary:**  
To evaluate the efficacy (clinical and mycological) of Clotrimazole (BAY B 5097).  
To investigate the local tolerance of Clotrimazole (BAY B 5097). |
| Evaluation Criteria: | **Efficacy (Primary):**  
At the end of the trial, the investigator assessed the result of the trial by correlating the clinical and mycological findings.  
Assessment 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 or mycological  
**Safety:**  
Tolerance by the subject of the test drug. |
| Statistical Methods: | **Efficacy (Primary) - if applicable:**  
The results for the subjects were given as percentages according to age, sex, diagnosis, mycological and clinical findings, and success of therapy.  
**Safety:**  
Statistical analysis of safety and tolerance was not planned. |
| Number of Subjects: | 30 to 50 subjects were planned to be studied.  
32 subjects were studied and evaluated. |
## Study Results

### Results Summary — Subject Disposition and Baseline

The efficacy and tolerance of Clotrimazole (BAY B 5097) were examined in an open, mycologically controlled study in 32 subjects with dermatomycoses.

The subjects were between 9 and 74 years of age, with an average of 37.5 years. Subjects were 40% male, 60% female.

The most frequent diagnoses were pityriasis versicolor in 14 subjects (44%), followed by tinea corporis in 11 subjects (34%), and other tinea infections in 22%. In 13 of 14 subjects with pityriasis versicolor, large areas were affected (50 to 1000 cm$^2$).

### Results Summary — Efficacy

Mycological findings: At the end of treatment, direct microscopy (wet film) was negative in 30 subjects (94%). No fungi were detectable on culture examination in any of the subjects at the end of treatment.

Clinical assessment: Therapeutic success based on clinical findings indicated that 60% of the subjects were "cured" and 40% showed "improvement". The assessment "cure" was more frequent for pityriasis than for the tinea forms.

### Results Summary — Safety

No side effects were observed. Subjects tolerated the study drug.

### Conclusion

In this study, Clotrimazole (BAY B 5097) had "good" therapeutic effect and was tolerated by all subjects.