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**Statistical Evaluation of an  
Application Study with  
Pefrakehl 6X Injectable Solution**

**in patients with mycoses**

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## 1. Introduction

From January 1995 to January 1996, a total of 75 patients suffering from mycoses were admitted to an observation study with Pefrakehl 6X Injectable Solution, a homeopathic remedy, in a medical practice. The test preparation Pefrakehl 6X consists exclusively of the 6th decimal dilution of *Candida parapsilosis* in an isotonic sodium chloride solution in accordance with methods 5b and 11, HAB.

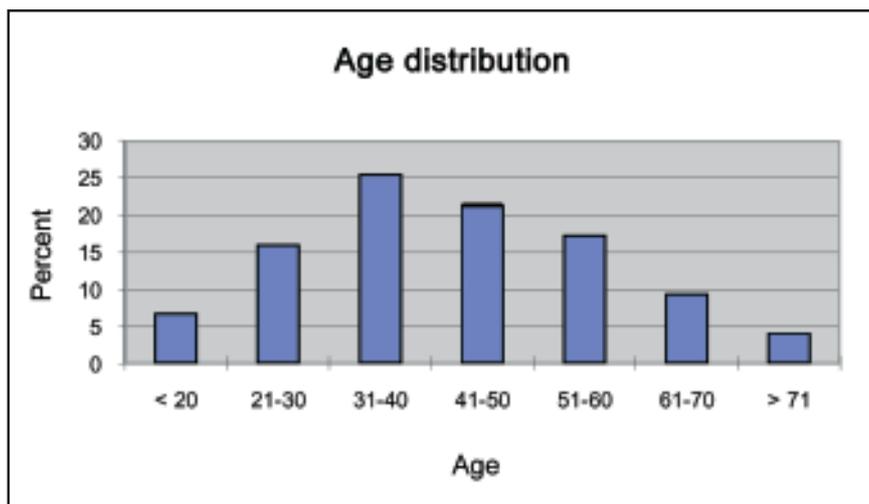
The aim of the observation study was to establish the actual application of the preparation and its efficacy under conditions of everyday practice. Further, knowledge concerning the acceptance of the product on the market should be gained.

In accordance with the structure of the study, exclusively descriptive statistical procedures were used. The application of inductive methods was not indicated. An "intention to treat" evaluation was carried out, i.e. all patients were considered, who had received at least one dose of the remedy.

## 2. Participating patients

75 patients with mycoses (Enteromycoses, Dermatomyces, Vaginal mycoses) participated in the study, 15 men (20%) and 60 women (80%).

The age of the patients varied between 18 and 91 years with an average of 43.0 years and a standard deviation of 15.1 years. 5 patients (6.7%) were younger than 20 years, 12 (16%) were



between 21 and 30 years. The biggest group was that of 31 to 40-year-old patients with 19 (25.4%), followed by the 41 to 50-year-old patients with 16 (21.3%). 13 patients (17.3%) were between 51 and 60 years old, 7 patients (9.3%) between 61 and 70 years, and 3 patients (4%) over 71 years old.

## 2.1 Diagnosis and accompanying diseases

According to the Study protocol, the prescriptions of the diagnoses to be treated were Enteromycosis, Dermatomyces and Vaginal mycosis in 25 patients each. Collected findings were carried out before and after completion of the treatment. Any accompanying therapies were to be documented in a survey form. No accompanying medication was administered to the 75 patients included in the study.

## 3. Dosage and duration of treatment

### 3.1 Time of consultation and duration of treatment

Corresponding to the nature of

an application study, the doctor was not given a fixed schedule for the initial and final examinations. The duration of treatment was on average 5.0 weeks  $\pm$  2.2 weeks with a minimum duration of 2 weeks and a maximum duration of 12 weeks. All patients participated in the final examination.

When the patients are divided into the three diagnosis groups "Enteromycosis", "Dermatomyces" and "Vaginal mycosis", significant differences regarding the therapy duration and the duration of complaints become apparent. The enteromycoses had persisted the longest with an average of  $10.0 \pm 11.1$  weeks and were also treated the longest of all three indication groups with  $6.6 \pm 2.4$  weeks. The dermatomyces had persisted for  $3.4 \pm 2.9$  weeks and were treated for  $5.1 \pm 2.0$  weeks. Naturally, the vaginal mycoses had persisted for relatively short periods with  $1.4 \pm 0.9$  weeks, and the therapy duration of this indication group was also the shortest with  $3.6 \pm 0.9$  weeks.

### 3.2 Dosage

Dosage was prescribed in the indication groups of enteromyces and vaginal mycoses with 2x 1 ml injection volume weekly. In the patients with dermatomyces, the dosage varied between a weekly injection volume of 1 and 2 ml with an average of 1 ml 1.9 ± 0.3 times weekly.

## 4. Efficacy and tolerance

### 4.1 Enteromyces

Of the 25 patients with enteromyces who participated in the study, 24 patients (= 96%) were free of complaints at the end of the therapy, e.g. apart from the missing symptoms, also the laboratory analysis detected no fungal presence. The condition of one patient (= 4%) was unchanged after a therapy duration of 5 weeks with a positive detection of fungal presence (stool) of *Candida pseudotropicalis*.

### 4.2 Dermatomyces

The efficacy picture in the 25 patients with dermatomyces was quite similar. Corresponding to the numerous findings of

*Candida* infections as well as eczema, pruritus, and desquamation, 12 patients (= 48%) were free of complaints at the end of the therapy. Another 10 patients (= 40%) had experienced significant improvement, 2 patients (= 8%) slight improvement. The eczematous skin alterations on both lower legs of a 46 years old female patient (= 4%) could not be influenced during the therapy duration of 5 weeks.

### 4.3 Vaginal mycoses

Of the 25 female patients with vaginal mycoses who participated in the study, 21 patients (= 84%) were free of complaints at the end of the therapy, e.g. apart from the missing symptoms, also the laboratory analysis detected no fungal presence. 3 patients (= 12%) experienced a slight improvement, and in one 37 years old patient (= 4%), no improvement of symptoms could be observed after a therapy duration of 3 weeks.

### 4.4 Evaluation of Efficacy

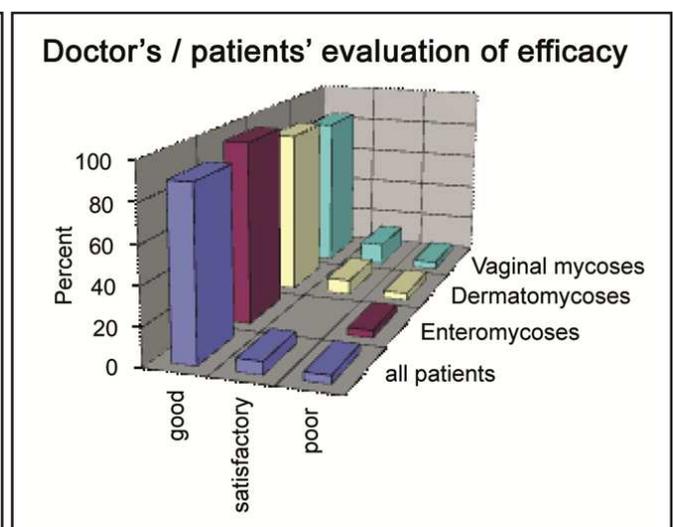
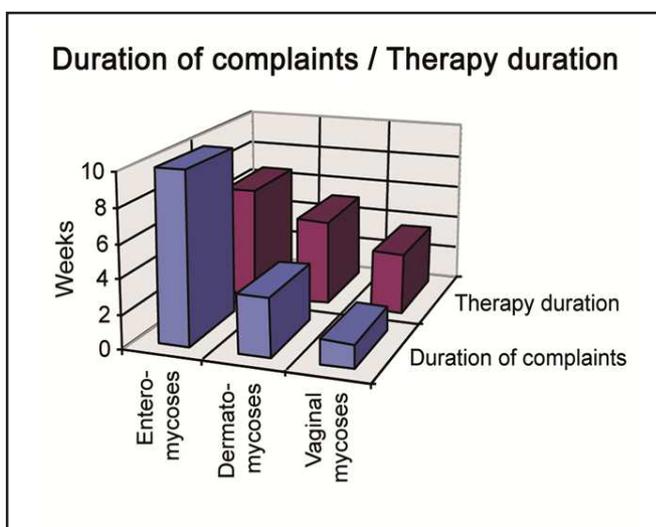
In a final assessment, doctors and patients were asked to evaluate efficacy and tolerance. Efficacy

could be rated as “good“, “satisfactory“ or “poor“. Globally, efficacy was rated as “good“ in 67 cases (= 89.3%), as “satisfactory“ in 5 cases (= 6.7%) and as “poor“ in 3 cases (= 4.0%) by both doctor and patients. The three “poor“ evaluations were submitted by the three non-responders to the therapy with Pefrakehl.

Within the three indications, efficacy was rated best in the enteromyces group. Here, doctor and patients settled for “good“ in 24 cases and for “poor“ in one case. In dermatomyces, doctor and patients rated as “good“ in 22 cases, as “satisfactory“ in two cases, and as “poor“ in one case. In vaginal mycoses, the result of the evaluation turned out a little worse: efficacy was rated as “good“ in 21 cases, as “satisfactory“ in 3 cases and as “poor“ in one case.

## 5. Tolerance

In the survey form, patients were enquired on possible initial aggravation, side effects and incompatibilities. No patient reported any initial aggravation,



side effects or incompatibilities even during the long treatment duration of a maximum period of 12 weeks in enteromycosis.

### 5.1 Evaluation of Tolerance

At the end of the examination, doctor and patients evaluated tolerance, which could be rated as “good“, “satisfactory“ or “poor“. For all 75 patients admitted to the study, both doctor and patients evaluated tolerance with “good“. No study was discontinued.

### 6. Summary

From January 1995 to January 1996, a total of 75 patients suffering from mycoses were admitted to an observation study with Pefrakehl 6X Injactable Solution, a homeopathic remedy, in a medical practice. The age of the patients varied between 18 and 91 years with an average of 43.0 years.

According to the Study protocol, the prescriptions of the diagnoses to be treated were Enteromycosis, Dermatomycosis and

Vaginal mycosis in 25 patients each. All 75 patients included in the study received a monotherapy with Pefrakehl 6X. No accompanying medication was administered.

The treatment duration was on average  $5.0 \pm 2.2$  weeks, with a minimal duration of 2 weeks and a maximum therapy duration of 12 weeks.

Dosage was prescribed in the indication groups of enteromycoses and vaginal mycoses with 2x 1 ml injection volume weekly. In the patients with dermatomycoses, the dosage varied between a weekly injection volume of 1 and 2 ml with an average of 1 ml  $1.9 \pm 0.3$  times weekly.

Progress of the treatment was determined by means of a collection of medical findings. At the end of the therapy, 96% of the patients with enteromycoses, dermatomycoses and vaginal mycoses each were free of complaints or had experienced

improvement. In one patient of each indication group, the test preparation showed no effect.

Of the 75 patients admitted to the study, 67 patients rated efficacy of the treatment as “good“, whilst 5 patients attested “satisfactory“ and 3 patients “poor“ efficacy to the preparation. The doctor's opinion was identical to that of the patients.

Both doctor and patients evaluated tolerance as “good“ without exception. No study was discontinued. Initial aggravations, side effects and incompatibilities were not observed.

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