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**Statistical Evaluation**  
**An Observation to the Application of the**  
**Preparation Series**  
**MUCOKEHL**

**In the Administration Forms of: Eye Drops, Capsules,  
Tablets, Drops, Suppositories, Solution for Injection**

**by Dr. Reiner Heidl**

## 1. Introduction

From March 1997 to October 1999, a total of 71 patients were tested by 11 Doctors' practices (6 General Practitioners, 3 Internists, 1 Ear, Nose and Throat Specialist and 1 Dentist) in an observation study with the application of the preparation series Mucokehl in the following administration forms: eye drops, capsules, tablets, drops, suppositories and solution for injection. The homeopathic test preparation Mucokehl comprising of the third to the seventh decimal dilutions of *Mucor racemosus* Fresen, each according to administration dosage.

Mucokehl drops contain *Mucor racemosus* 5X dil. in accordance with Prescription 5a HAB1.

1 ampoule of Mucokehl solution for injection contains 1 ml *Mucor racemosus* 5X (*Mucor racemosus* 6X and *Mucor racemosus* 7X respectively) aquos. dil. in accordance with Prescription 5b and 11 HAB 1.

1 Mucokehl capsule contains: 330 mg *Mucor racemosus* 4X trit. in accordance with Prescription 6 HAB 1.

1 Mucokehl suppository contains: 0.2 g *Mucor racemosus* 3X trit. in accordance with Prescription 6 HAB 1.

5 ml Mucokehl eye-drops contain: 4,999.95 mg *Mucor racemosus* 5X dil. in accordance with Prescription 5a and 15 HAB 1.

The aim of the observation was to establish the actual application of

the preparations and their tolerance under conditions in every-day practice, moreover that recognition over the acceptance of the preparations on the market should be gained, in particular with children.

In accordance with the structure of the investigation exclusive descriptive statistical procedures were drawn. The application of inductive methods was not indicated. An "intention to treat" assessment was carried out, i.e. all patients were considered who had received at least one dose of the medicament.

## 2. Participating Patients

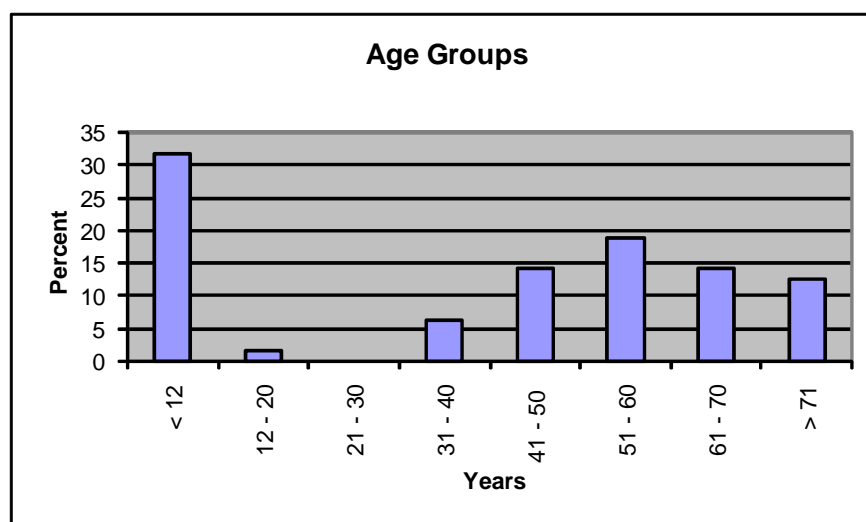
Included in the study were 71 patients which comprised of 51.6% men and 48.4% women. The age of the patients varied between 8 months and 82 years with an average of 40.4 years and a standard deviation of 26.8 years. Almost a third of the patients (31.7%) were under 12 years of age. Between the ages of 13 and 20 amounted to 1.6% of the patients. There were no patients in the age group between 21 and 30 years. Between the ages of 31 and 40, 6.3% and between 41 and 50

years were 14.3%. Apart from the age group under 12 years, the age group of 51 to 60 years was the largest group with 19%. From 61 to 70 years were 14.3% and finally over 71 years made up 12.7 of the patients. The age structure of the men was classified with an average age of  $41.3 \pm 24.9$  years similar to the women with  $39.5 \pm 26.7$  years.

Height varied between 98 and 183 cm with an average of  $160.0 \pm 21.2$  cm. Body weight lay between 20 and 88 kg with an average of  $62.9 \pm 20.2$  kg.

### 2.1 Diagnosis and Accompanying Diseases

The prescription of the diagnosis to be treated was to be entered into the Study protocol. It was herewith set out that Mucokehl corresponding to Isopathy in a very wide area of application be applied and the preferred use dependent on the age of the patients. Whilst Mucokehl was mainly applied in the younger patient groups under 12 years with allergic occurrences such as food intolerance and neurodermatitis, patients in the over 12 age group stood in the foreground with



diseases such as hypertony, chronic pain syndrome, arterial closure and LWS syndrome. Collected findings were carried out each before and after completion of the treatment and accompanying therapies to be documented in a survey form.

In order to obtain a measurement of chronic diseases, it was asked in the study protocol, how long the disease or discomfort had been in existence. Whilst doing this, a time span of less than 6 months, up to 1 year, up to 3 years and over 3 years was laid down. The duration of complaints of less than 6 months accounted for 16 patients (27.1%), 5 patients (8.5%) between 6 and 12 months and for 6 patients (10.2%) up to 3 years. Over half the patients (32 patients = 54.2%) suffered discomfort for over 36 months. It was astonishing to find this high percentage of sufferers of over three years both in the patient groups of younger than 12 years and older than 12 years. There are no details for 12 of the patients.

Of the 71 patients included in the study, 13 patients (6 patients < 12 years, 7 patients > 12 years) were previously treated with Mucokohl.

### 3. Dosage and Duration of Treatment

#### 3.1 Time of Consultation and Duration of Treatment

Corresponding to the nature of application observations no rigid time limit was laid down for a final examination which was carried out in a time span between 7 and 457 days with an average of  $80.6 \pm 98.0$  days.

Duration of the therapy in children (< 12 years) was on average  $91.8 \pm 98.6$  days, almost a third longer than those in the adult group of  $66.5 \pm 76.4$  days. The brief therapy was predominant with 48.6 % of the adult patients, whilst a therapy period between 51 and 75 days with the children was the maximum expression available in 36.8 % of all cases.

#### 3.2 Dosage

The dosage was prescribed for the relevant form of administration according to the package insert with:

##### MUCOKEHL Drops

For oral intake: 1 x 8 drops daily before mealtimes

For inhalation: 2-3 x daily 20-30 inhalations

For topical application:

a) 1 x daily 5-10 drops at the location of the complaint or massage into the crease of the elbow.

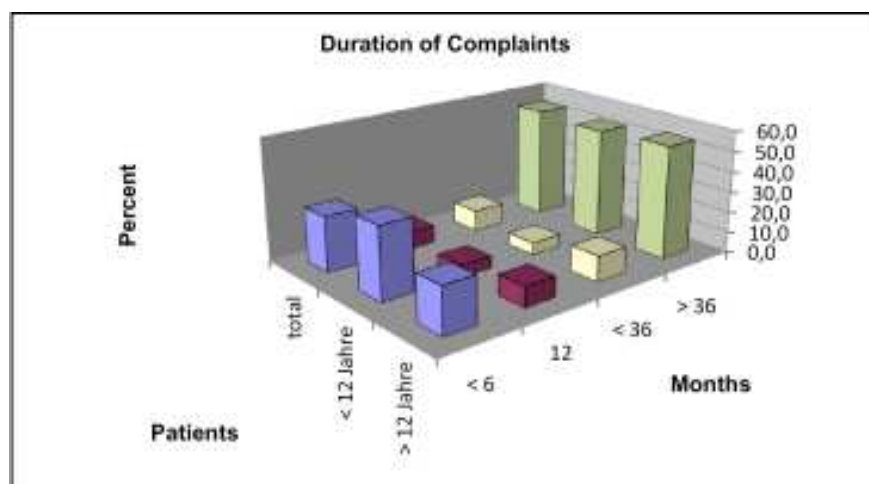
b) By injection treatment; on injection free days 2 x weekly 5-10 drops

##### MUCOKEHL Solution for Injection

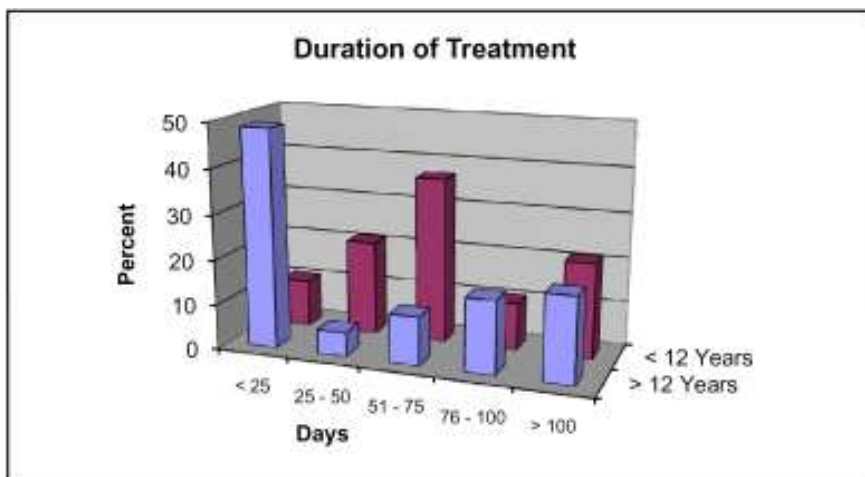
2 x weekly, inject 1.0 ml either i.m., s.c., i.c., or i.v.

##### MUCOKEHL Capsules

Daily 1-3 capsules either before breakfast or evenings before bedtime to be taken with some fluid.



| Duration of Complaints (Months) | Total Patient Population (%) | Patients < 12 years (%) | Patients > 12 years (%) |
|---------------------------------|------------------------------|-------------------------|-------------------------|
| < 6                             | 27.1                         | 35.3                    | 22.5                    |
| 6 - 12                          | 8.5                          | 5.9                     | 10                      |
| < 36                            | 10.2                         | 5.9                     | 12.5                    |
| > 36                            | 54.2                         | 52.9                    | 55                      |



sults in a medium dosage of  $7.5 \pm 1.1$  drops, a minimum dosage of 5 drops and a maximum dosage of 8 drops. Besides the mono-therapy with one administration form, two administration forms were also combined into the therapy. Because the injection was applied in weekly rotation, in addition to the injection free time, 4 patients were given capsules, 3 patients tablets, and 6 patients drops for oral intake. Drops were orally consumed as well as topically applied by 8 patients. A combination of more than two administration forms was not applied. There was a clear difference in both age groups in the extent of the combination of the dosage forms. The under 12 age group were exclusively administered with drops for oral intake and topical application combined, whilst the patients in the over 12 age group a combination of solution for injection and dosage forms for oral intake was applied.

**MUCOKEHL Suppositories**  
1 x daily before bedtime 1 suppository to be inserted rectally.

**MUCOKEHL Eye Drops**  
2 x daily trickle 1 drop into the affected eye.

With reference to the dosage forms, 9 patients were prescribed capsules, 12 patients with tablets, 20 patients with drops for oral intake, 9 patients with drops for topical application, 1 patient with drops for inhalation, 6 patients with suppositories, 1 patient with eye drops and 24 patients with the solution for injection. Multiple entries were necessary if various administration forms were to be combined. The

table below shows the medium dosage with respect to the administration form. Injection volumes were administered for one week and the remaining dosage forms were prescribed to the relevant daily dosage.

Nothing else was substantially administered for the under and over 12 age groups. The dosage of the drops for oral intake seems at first glance higher in the adult group. It is however for this reason that in two cases, patients were conditionally treated with a daily dosage of 50 drops, which corresponded to 6 times the recommended dosage. When both of these departures are not taken into consideration, it re-

#### 4. Comparison with Earlier Therapy

6 patients had already received therapy with one or several administration forms of Mucokehl within the last five years. Although

| Total population | Medium Dose     | Minimum Dose | Maximum Dose |
|------------------|-----------------|--------------|--------------|
|                  | Eye drops       | 2.0          | 2            |
| Capsules         | $2.0 \pm 0.8$   | 1            | 3            |
| Tablets          | $2.7 \pm 1.2$   | 1            | 5            |
| Drops (oral)     | $11.1 \pm 12.7$ | 4            | 50           |
| Drops (topical)  | $6.8 \pm 1.3$   | 4            | 8            |
| Drops (inhale)   | 24.0            | 24           | 24           |
| Suppositories    | 1.0             | 1            | 1            |
| Injection (ml)   | $2.4 \pm 1.7$   | 0.5          | 6            |



### All patients < 12 years

|                 | Medium Dose | Minimum Dose | Maximum Dose | No. of Patients |
|-----------------|-------------|--------------|--------------|-----------------|
| Eye drops       | 1.0         | 1            | 1            | 1               |
| Drops (oral)    | 6.8 ± 1.4   | 4            | 8            | 12              |
| Drops (topical) | 6.7 ± 1.4   | 4            | 8            | 9               |
| Drops (inhale)  | 24          | 24           | 24           | 1               |
| Suppositories   | 1.0         | 1            | 1            | 3               |

### All patients > 12 years

|                | Medium Dose | Minimum Dose | Maximum Dose | No. of Patients |
|----------------|-------------|--------------|--------------|-----------------|
| Eye drops      | 2.0         | 2            | 2            | 1               |
| Capsules       | 2.3 ± 0.7   | 1            | 3            | 7               |
| Tablets        | 2.7 ± 1.2   | 1            | 5            | 12              |
| Drops (oral)   | 18.1 ± 18.4 | 5            | 50           | 8               |
| Suppositories  | 1.0         | 1            | 1            | 3               |
| Injection (ml) | 2.4 ± 1.7   | 0.5          | 6            | 24              |

this group was very small, both the patient groups of the First and Multiple Users were compared with respect to effectiveness and tolerance. From the data on tolerance, the possibility of tendencies towards sensitisation from the pharmaceutical effective components should be possible.

Opinion to tolerance by multiple application was substantially better than that of a single application. Doctors and patients in the group of Multiple Users gave an assessment of "very good" and

"good". The designation of "very good" tolerance was substantially more pronounced in this group than with the total average. From this data, it is shown that there was no potential of an exposure to danger regarding sensitisation to patients through the pharmaceutical effective component of *Mucor racemosus*.

The Multiple Users judged the effectiveness in keeping with the trend better in the assessment "very good" than the First Users, just as no multiple user gave an assessment of "moderate" effec-

tiveness and "no effect". The duration of the therapy is also distinguished by the Multiple Users with an average therapy duration of 46.5 ± 27.7 days, approximately 33 days compared with the average reduced therapy. The First Users were treated for an average of 90.5 ± 108.2 days.

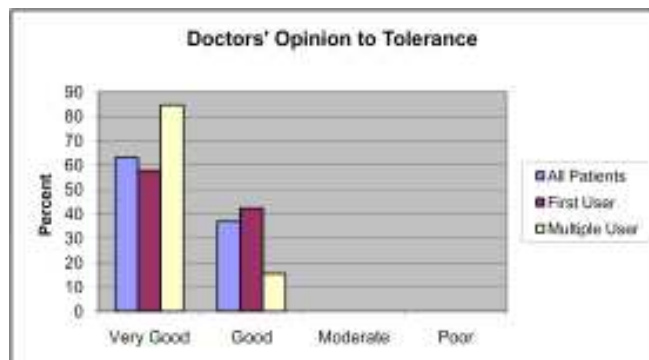
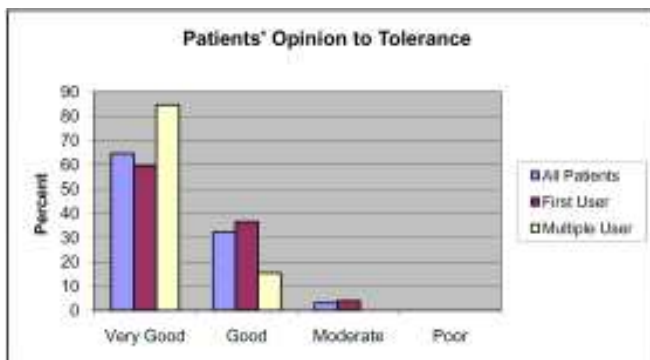
## 5. Effectiveness and Tolerance

### 5.1 Assessment of Effectiveness by Doctor and Patient

In a closing assessment, doctors and patients were asked to judge

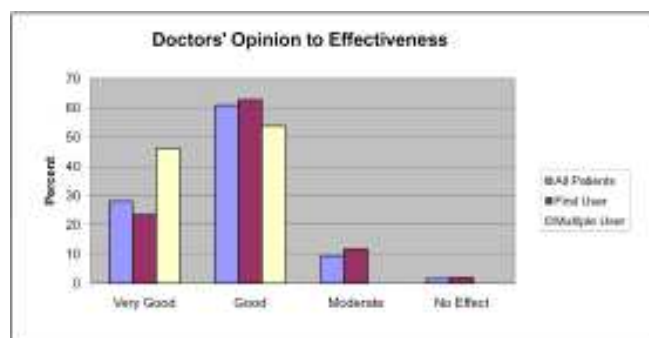
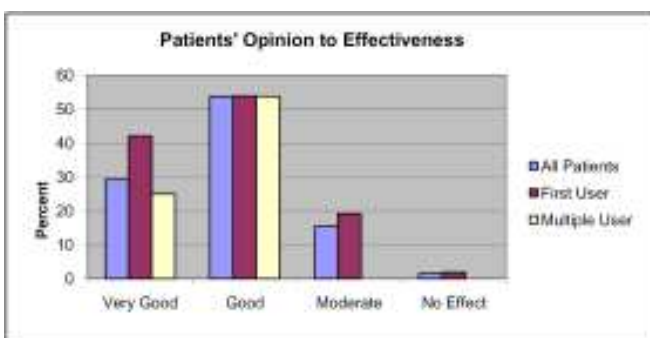
### Opinion to Tolerance

| Patient Group | Patients' Opinion (%) |      |          |      | Doctors' Opinion (%) |      |          |      |
|---------------|-----------------------|------|----------|------|----------------------|------|----------|------|
|               | Very Good             | Good | Moderate | Poor | Very Good            | Good | Moderate | Poor |
| All Patients  | 64.6                  | 32.3 | 3.1      | 0    | 63.1                 | 36.9 | 0        | 0    |
| First User    | 59.6                  | 36.5 | 3.9      | 0    | 57.7                 | 42.3 | 0        | 0    |
| Multiple User | 84.6                  | 15.4 | 0        | 0    | 84.6                 | 15.4 | 0        | 0    |



### Opinion to Effectiveness

| Patient Group | Patients' Opinion (%) |      |          |      | Doctors' Opinion (%) |      |          |      |
|---------------|-----------------------|------|----------|------|----------------------|------|----------|------|
|               | Very Good             | Good | Moderate | Poor | Very Good            | Good | Moderate | Poor |
| All Patients  | 29.2                  | 53.8 | 15.4     | 1.5  | 28.1                 | 60.9 | 9.4      | 1.6  |
| First User    | 25.0                  | 53.9 | 19.2     | 1.9  | 23.5                 | 62.7 | 11.8     |      |
| Multiple User | 46.2                  | 53.8 | 0        | 0    | 46.2                 | 53.8 | 0        |      |

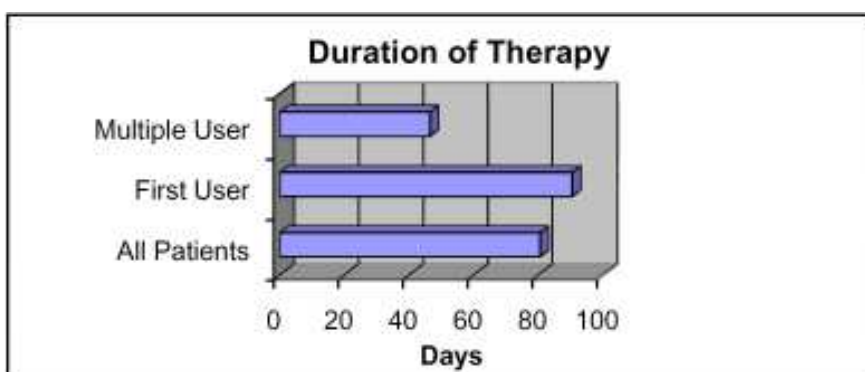


the effectiveness and tolerance. The effectiveness could be assessed with "very good" "good" "moderate" or "no effect". In addition, the doctors were asked according to the patient's compliance to usage, so that it could also be classified with "very good", "good", "moderate" or

"poor". 29.2% of patients expressed effectiveness with "very good", 53.9% with "good", whilst 15.4% expressed only "moderate" and 1.5% with "no effect". The doctors' assessment to effectiveness was just as positive as with the patients. 28.1% of patients were

classified with "very good", 60.9% with "good", 9.4% with "moderate" and 1.6% with "no effect".

Application behaviour (N=53) was judged by 31 patients with "very good" and "good" by 20 patients through their doctor. With it, 71.8% of all those patients involved in the study confirmed very good compliance. This was only "moderate" for two patients and "poor" for none of the patients.



### 5.2 Opinion of Tolerance by Doctor and Patient

To conclude the examination, an assessment to tolerance was submitted from doctors and pa-

tients, whereby a judgement of "very good", "good", "moderate" and "poor" could be chosen. 63.5% of patients and 58.1% of doctors classified the tolerance with "very good" whilst 33.3% of patients and 38.7% of doctors confirmed a good tolerance with Mucokehl. A "moderate" tolerance was given by 3.2% of patients and doctors. No patient or doctor gave a classification of "poor".

the percentage of "all patients", as with the rubrik, "all patients" and the patients included for whom no age designation was listed.

### 5.3 Side Effects and Discontinuation of the Therapy

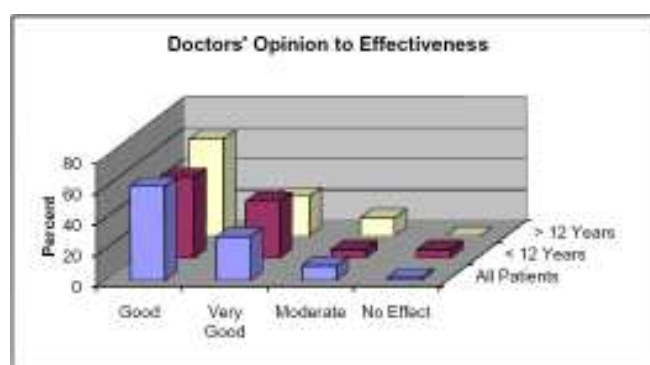
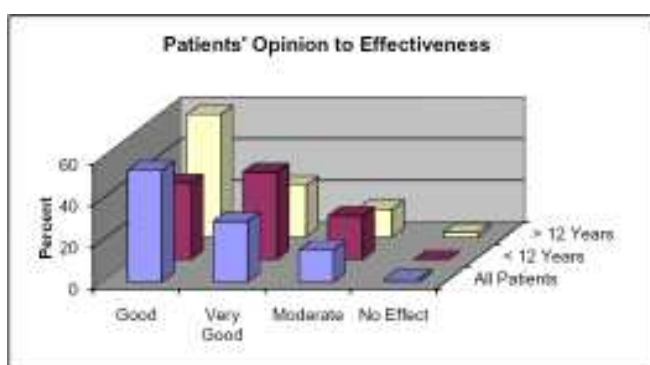
The therapy with Mucokehl was not discontinued by any of the patients. However, 8 unwelcome pharmaceutical effects were reported which are more closely interpreted as

who were older than 12 years.

By a 43 year old patient, constant but no serious pain appeared in the knees after 8 days into the therapy, which disappeared again after the therapy was discontinued. As to whether there was a connection with the knee pain and the Mucokehl therapy remains doubtful, as a diagnosis in the Anamnese "chondropathia patellae bds" was entered.

### Opinion to Effectiveness

| Patient Group | Patients' Opinion (%) |      |          |           | Doctors' Opinion (%) |      |          |           |
|---------------|-----------------------|------|----------|-----------|----------------------|------|----------|-----------|
|               | Very Good             | Good | Moderate | No Effect | Very Good            | Good | Moderate | No Effect |
| All Patients  | 29.2                  | 53.8 | 15.4     | 1.5       | 28.1                 | 60.9 | 9.4      | 1.6       |
| < 12 Years    | 42.1                  | 36.8 | 21.1     | 0         | 36.8                 | 52.6 | 5.3      | 5.3       |
| > 12 Years    | 25.0                  | 59.1 | 13.6     | 2.3       | 25.6                 | 62.8 | 11.6     | 0         |



Tolerance was by far more positively assessed by doctors and patients in the under 12 age group than with the over 12 age group. Whilst in the younger age groups 80% of the patients and doctors indicated tolerance with "very good", this was with the over 12's only 55.8% of patients and 50.0% of doctors. The doctors assessed no cases of "moderate" or "poor" in both the under and over 12 age groups. The total of the percentages of the under and over 12 age groups must not inevitably prove

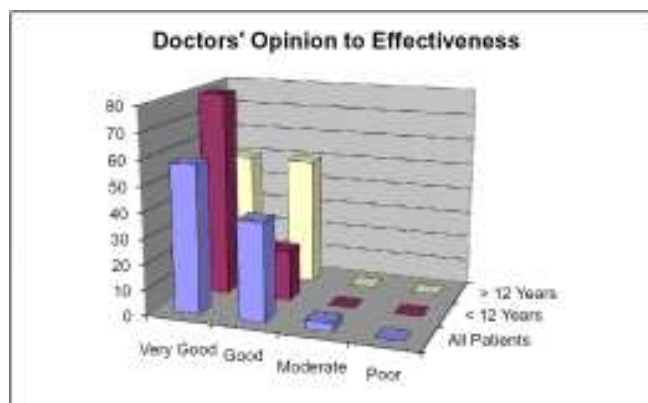
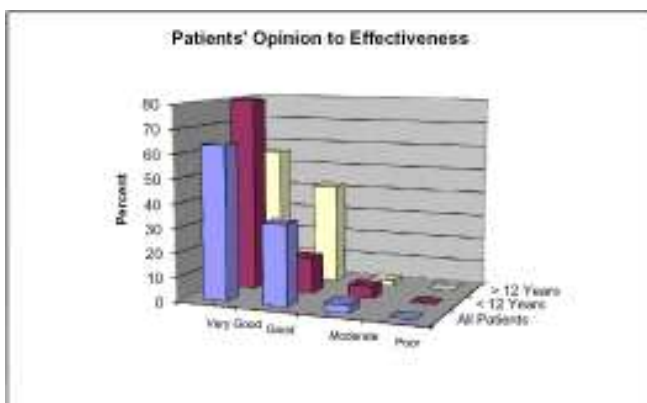
follows: 6 cases of influenza were reported as a side effect. A connection with the use of Mucokehl was rejected and the infection was symptomatically treated. The 6 patients and their Doctors classified tolerance as "very good". It can also be seen that the appearance of influenza infections must not be brought into connection with the Mucokehl therapy. In the under 12 age group in the described side effects, a 7 year old girl had contracted influenza. All other reports are only related to patients

An 8 months old baby girl prescribed with Mucokehl drops for oral intake as well as topical application developed a light diarrhoea 10 days after start of the therapy and which disappeared again without further treatment. The question remains whether the diarrhoea was related to the Mucokehl.

Side effects were listed with the various administration forms. With the Mucokehl solution for injection, 4 cases of local irritation occurred

## Opinion to Tolerance

| Patient Group | Patients' Opinion (%) |      |          |           | Doctors' Opinion (%) |      |          |           |
|---------------|-----------------------|------|----------|-----------|----------------------|------|----------|-----------|
|               | Very Good             | Good | Moderate | No Effect | Very Good            | Good | Moderate | No Effect |
| All Patients  | 63.5                  | 33.3 | 3.2      | 0         | 58.1                 | 38.7 | 3.2      | 0         |
| < 12 Years    | 80.0                  | 15.0 | 5.0      | 0         | 80.0                 | 20.0 | 0        | 0         |
| > 12 Years    | 55.8                  | 41.9 | 2.3      | 0         | 50.0                 | 50.0 | 0        | 0         |



at the point of needle insertion which disappeared again without further therapy. The 4 patients and their doctors nevertheless assessed the tolerance with "very good" and "good". For 3 patients administered with oral administration forms reported "sweating" as a side effect. 2 of the 3 patients, however, also suffered simultaneously from influenza. The third patient, a 48 year old woman with recurrent phlebothrombosis reported "sweating" and "itching" which occurred between the second and fifth injection, as well as an irritation at the point of needle insertion (subcutaneous) between the first and eighth injection. The symptoms, however, were not so pronounced that further therapy measures had to be taken.

After subcutaneous injection, a local reaction of "Itching with erythema" occurred in a 44 year old patient

from the second to the 26th day of treatment, however, an intervention was not recommended. After oral application of Mucokehl drops, two patients reported "burning in the mouth" and "reddening of the mucous membrane". That both these patients suffered from paradontosis, they cannot be classified as side effects and both patients described tolerance as "good".

In total, no extreme dominant reactions appeared. All those side effects reported were completely reversible.

### 6. Summary

From March 1997 to October 1999, a total of 71 patients were tested by 11 Doctors' practices (6 General Practitioners, 3 Internists, 1 Ear, Nose and Throat Specialist and 1 Dentist) in an observation study with the

application of the preparation series Mucokehl in the following administration forms: eyedrops, capsules, tablets, drops, suppositories and solution for injection.

The age of the patients varied between 8 months and 82 years. Almost a third of the patients were under 12 years of age. Mucokehl was applied according to isopathy in a very broad area of application, whereby the preferred use was dependent on the age of the patients. In the younger patient group under 12 years, Mucokehl was mainly applied with allergic occurrences such as food intolerance and neurodermatitis. In the over 12 age group diseases such as hypertony, chronic pain syndrome, arterial closure illness and LWS syndrome were predominant. Accompanying therapies were to be documented in the survey form.





The duration of the therapy for children (<12 years) was on average  $91.8 \pm 98.6$  days, around a third longer as with the adult group with  $66.5 \pm 76.4$  days. Progress of the treatment was in each case determined at the beginning and end of the therapy.

83.1 % of the patients and 89.0 % of the doctors described the effects of the treatment as "very good" and "good". Tolerance was classified by 96.8 % of the patients and doctors each with "very good" and "good".

It gave no break-off in the study. No serious side effects were observed. Side effects and intolerance was documented. These were all (mostly without additional therapy) completely reversible.

A connection with the Mucokehl therapy could be made up in only 4 of the cases where irritation at the point of needle insertion occurred. Tolerance and effectiveness in the under 12 age group was substantially more positively judged as with the over 12 age group.

**First published in the German language in the SANUM-Post magazine (65/2003)**

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