



Statistical Evaluation
of an Application Study with the Preparation Series

Utilin H 5X

in the administration forms: capsules and suppositories

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1 Introduction

A total number of 184 patients in two medical practices, one specialising in general medicine and one in internal medicine, participated between January 1997 and February 2001 in an application study with the preparation Utilin H 5X capsules and suppositories. The homeopathic test preparation, Utilin H 5X, consists exclusively of *Bacillus subtilis* in the 5th decimal potency.

1 Utilin H 5X capsule contains: 330 mg *Bacillus subtilis* 5X trit. in accordance with provision 6, HAB.
1 Utilin H 5X suppository contains: 0,2 g *Bacillus subtilis* 5X trit. in accordance with provision 6, HAB.

The aim of this application study was to determine the actual application of the preparation as well as its tolerance under day to day conditions of a normal practice. It was also of importance to determine the acceptance of the preparation on the market, especially amongst children.

In line with the study's set-up, only descriptive statistical methods were used. The application of inductive methods was not indicated. An „intention-to-treat“ evaluation was carried out, which means that only patients who had already received at least one dose of the medicament were considered to be included in the study.

2 Participating Patients

184 patients participated in the study, comprising of 68 males (36.9%) and 116 females (63.1%).

The age of the patients varied between 6 and 78 years, with an average age of 47.6 and a standard deviation of 17.9. The groups under 12 years (6.5%), between 13 and 20 (5.4%) and between 21 and 30 (5.4%) were almost of the same size. Between 31 and 40 15.4% and between 41 and 50 12% of the patients. The largest group of patients was between 51 and 60 (27%), followed by those aged between 61 and 70 (20.1%). Patients over 70 accounted for 7.1%. In the age structure, men with an average age of 50.4 ± 17.6 were on average 5.5 years older than the women with 45.9 ± 17.9 years.

Size varied between 120 cm and 190 cm with an average height of $168.4 \text{ cm} \pm 10.9 \text{ cm}$. Weight varied between 22 kg and 99 kg with an average of $70.4 \pm 13.9 \text{ kg}$.

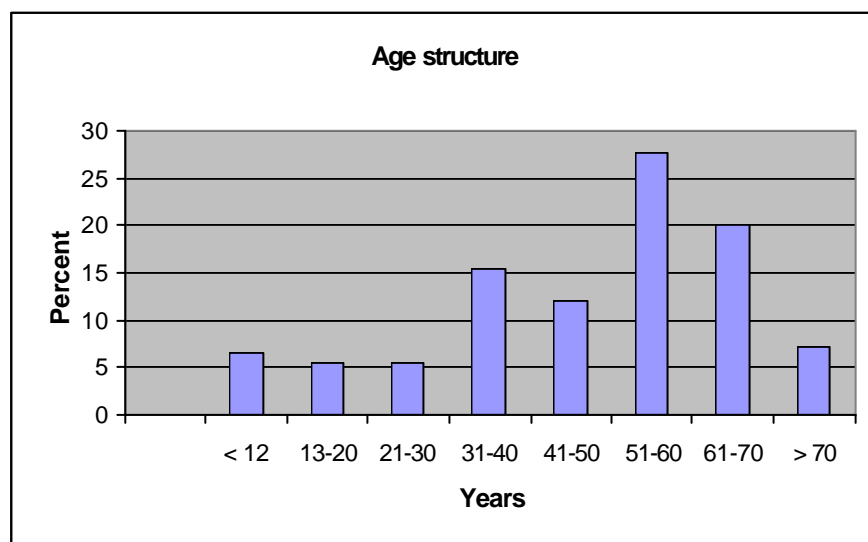
2.1 Diagnoses and Secondary Diseases

The diagnosis leading to the prescription was to be entered in the study protocol. It showed that Utilin H 5X, according to Isopathy, is used

in a very wide applicational range. The preferred application was independent of the patient's age. The main indications were bronchitis, lowered resistance and postmenstrual complaints. Accompanying therapies were to be documented in the evaluation form before and after treatment.

In order to obtain a measure for chronic diseases, the patients were asked in the study protocol how long they have endured the disease or complaints. Time-frames were given of less than six months, up to one year, up to three years and more than three years.

In 8.2% of the patients the complaints lasted less than 6 months, in 16.3% for a period between 6 and 12 months and in 21.2% for a period between 1 and 3 years. More than half of the patients (54.3%) had suffered for over 36 months. In the patient group under 12 years 16.7% suffered for less than 6 months and 16.7% for a period between 1 and 3 years. In this group no patient suffered for more than 3 years and two thirds suffered for a period between 6 and

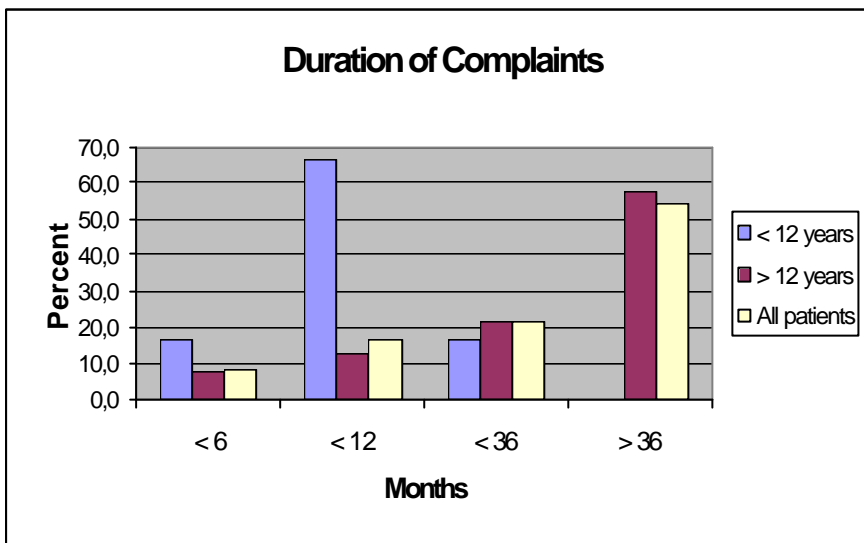




Duration of Complaints (Months)	Patients < 12 years (%)	Patients > 12 years (%)	Total Patient Population (%)
< 6	16.7	7.6	8.2
6-12	66.6	12.8	16.3
< 36	16.7	21.5	21.2
> 36	0	58.1	54.3

12 months. In the adult group over 12 years, chronic complaints between one and three years (21.5%) and for more than three years (58.1%) were predominant.

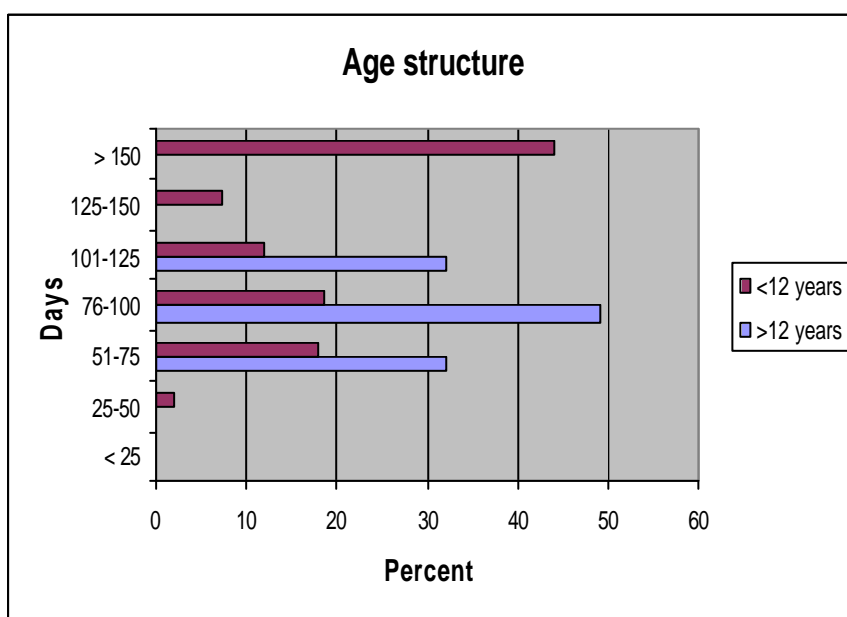
Of all the 184 patients participating in the study, 7 patients (2 patients > 12 and 5 patients < 12) had already previously been treated with Utilin H 5X.



3. Dosage and Therapy Duration

3.1. Consultation Times, Therapy Duration

According to the nature of an application study, the physician was not given a preset time-limit for the final patient assessment. Final examinations were conducted after a period of between 41 and 301 days, with an average value of 147.0 days ± 76.4 days.



Amongst the children (< 12 years), the therapy lasted 85.3 days ± 18.1 days and was half the treatment period shorter than in the adult group with 151.3 days ± 77.1 days. For only 3 patients of both groups, the therapy duration was under 50 days. In 50% of the younger patients under 12, a therapy duration between 76 and 100 days was predominant, whilst amongst the adults 45% of all patients were treated longer than 150 days.

3.2 Dosage

The dosage for each administration form was set as follows, according to the patient information leaflet:



Total population			
	Medium Dose	Minimum Dose	Maximum Dose
Capsules daily	1.0	1	1
Capsules weekly	1.7 ± 0.5	1	2
Suppositories daily	1.0	1	1
Suppositories weekly	1.7 ± 0.9	1	6

Contrary to the recommended dosage, five patients in the age group older than 12 years were treated daily with suppositories and capsules instead of weekly. The dosage is indicated as age-conformal. In the adult group, the weekly dosage of capsules and suppositories was 1.7 x higher than in the group under 12 years.

All patients under 12 years				
	Patients	Medium Dose	Minimum Dose	Maximum Dose
Capsules daily	0	0	0	0
Capsules weekly	12	10	1	1
Suppositories daily	0	0	0	0
Suppositories weekly	12	2.0±0.8	1	3

4 Comparison to Previous Therapy

Seven patients were treated with one or more administration forms of Utilin H 5X during the past five years, whereby four patients took a combination of capsules and suppositories, two patients only suppositories and one patient only capsules. By a comparison of efficacy and tolerance in both patient groups of first-time application users and repeated application users, a possible sensitisation towards the active ingredient should be determined.

All patients over 12 years				
	Patients	Medium Dose	Minimum Dose	Maximum Dose
Capsules daily	4	1.0	1	1
Capsules weekly	162	1.7 ± 0.4	1	2
Suppositories daily	1	1.0	1	1
Suppositories weekly	167	1.7 ± 0.9	1	6

With respect to the evaluation of tolerance, there were no significant differences concerning the evaluation between repeated application users and first-time users. Repeated application users assessed tolerance exclusively with „very good“. In both groups neither physicians nor patients rated it as „moderate“ or „no effect“. From this data, no potential danger concerning patient's sensitisation by the ingredient *Bacillus subtilis* D5 could be determined.

Utilin H 5X capsules:

Therapy: 1 capsule every 2 weeks as a medium dosage. In cases of slight or no response, administration may be increased to a maximum of 2 capsules per week.

Utilin H 5x suppositories:

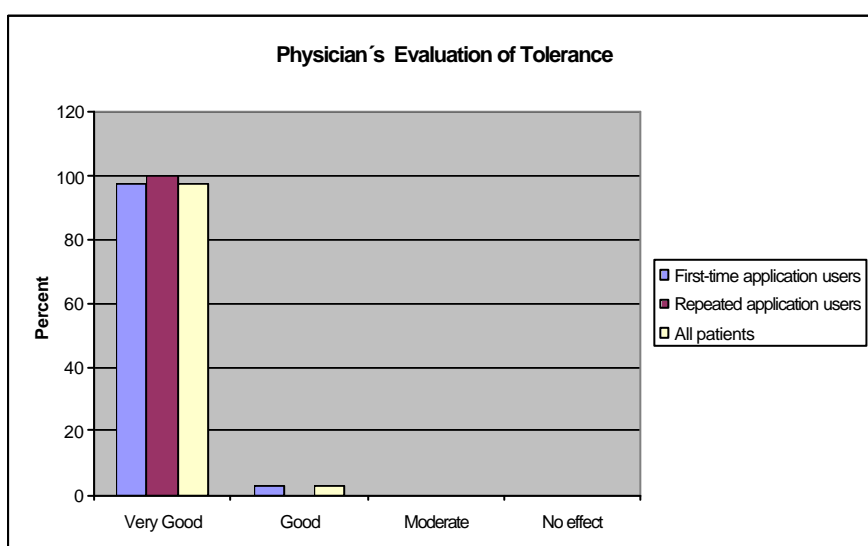
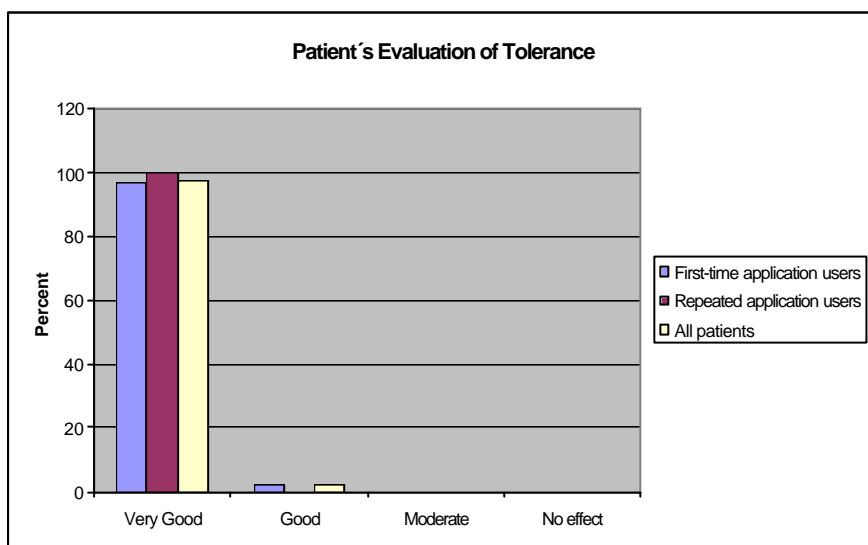
1 to 3 suppositories weekly to be rectally inserted before bedtime.

With respect to the administration forms, four patients took the

capsules daily and 174 patients weekly. One patient took the suppositories daily and 179 patients weekly. Multiple counts were necessary if both administration forms were combined. Altogether, capsules and suppositories were combined in 174 patients (= 94.6% of all patients). The medium dosage based on the form of application is shown in the following table.

The first-time users assessed efficacy as „very good“ and

Evaluation of Tolerance								
Patient Group	Patient's evaluation (%)				Physician's evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
First-time-application users	97,7	2,3	0	0	97,2	2,8	0	0
Repeated application users	100,0	0	0	0	100,0	0	0	0
All patients	97,8	2,2	0	0	97,3	2,7	0	0



according to tendency, better than the repeated application users. Neither physicians nor patients rated it with „no effect“.

Concerning the therapy duration, the difference between repeated application users with a medium therapy duration of 86.4 ± 14.4

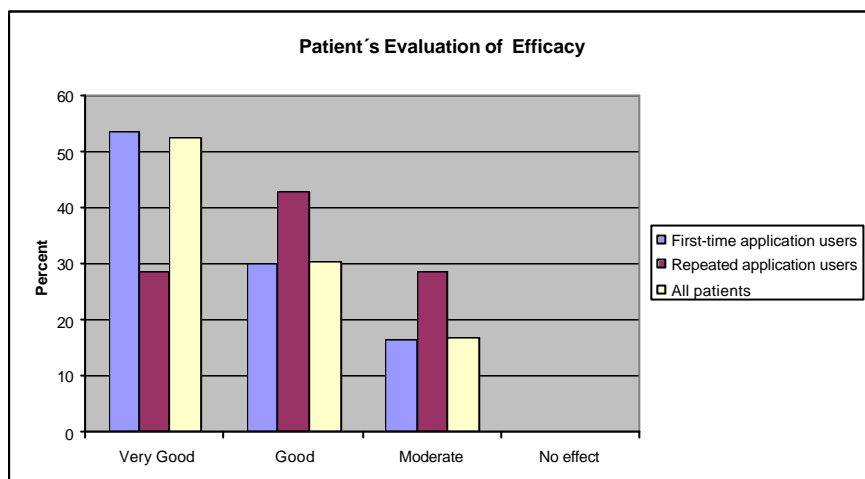
days, first-time users of 149.4 ± 76.9 days and the total of all patients of 147.0 ± 76.4 days is significant.

5 Efficacy and Tolerance

5.1 Evaluation of Efficacy by Physician and Patient

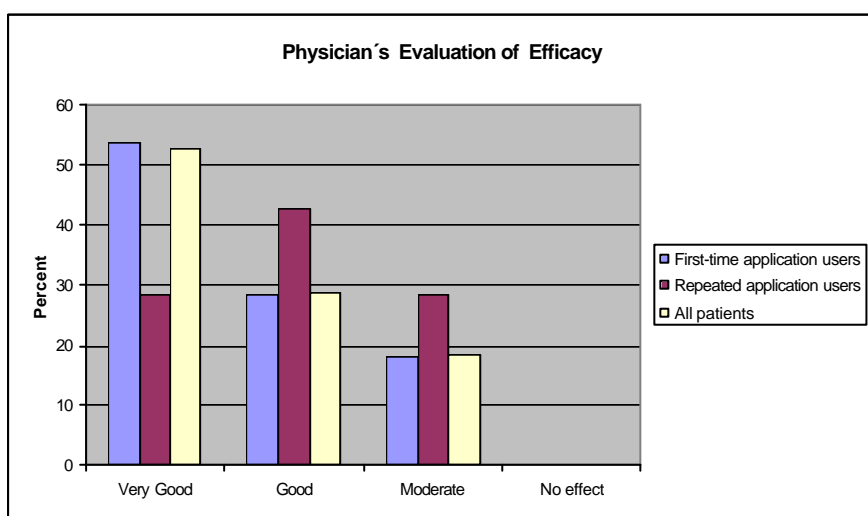
In a closing assessment, physicians and patients were asked to evaluate efficacy and tolerance. Efficacy could be assessed with „very good“, „good“, „moderate“ or „no effect“. The physicians were also requested to evaluate patient's compliance with „very good“, „good“ and „moderate“ or „non-compliant“. The evaluation of efficacy showed that 52.7% of the patients thought efficacy to be „very good“ and 30.4% „good“, whilst 16.9% assessed evaluation with „moderate“. The results of the physician's evaluation for efficacy was similarly positive as that of the patients. The physicians evaluated efficacy in 52.7% of the cases as „very good“ and 28.8% as „good“ and 18.5% as moderate. With „no effect“ evaluated neither physician nor patient. The evaluation by physicians and patients alike was according to tendency better in the under 12 group, as in this group evaluation was exclusively rated with „very good“ and „good“.

Evaluation of Efficacy								
Patient Group	Patient's evaluation (%)				Physician's evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
First-time-application users	53,7	29,9	16,4	0	53,7	28,3	18,0	0
Repeated application users	28,6	42,9	28,5	0	28,6	42,9	28,5	0
All patients	52,7	30,4	16,9	0	52,7	28,8	18,5	0

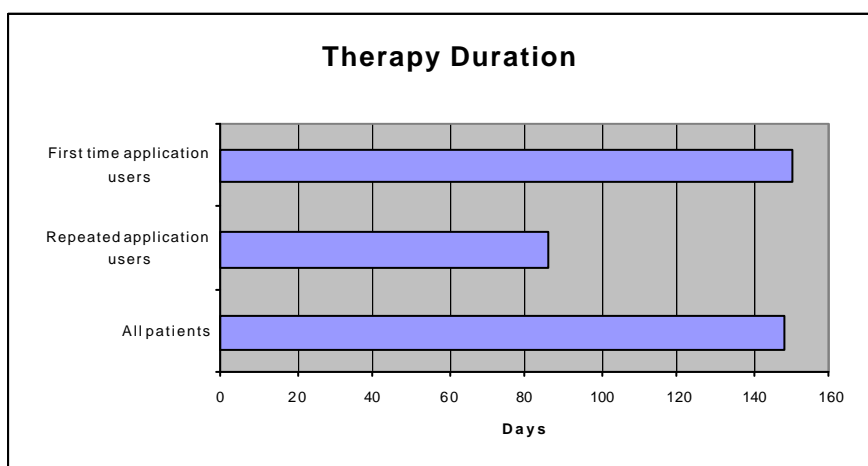


Compliance (N = 184) was assessed by the physicians to be „very good“ for 156 patients and „good“ for 26, hence 98.9% of all patients participating in the study were given a „good“ or „very good“ compliance rating. For two patients the compliance was assessed as „moderate“ and „non-compliant“ for no patient.

5.2 Evaluation of Tolerance by Physician and Patient

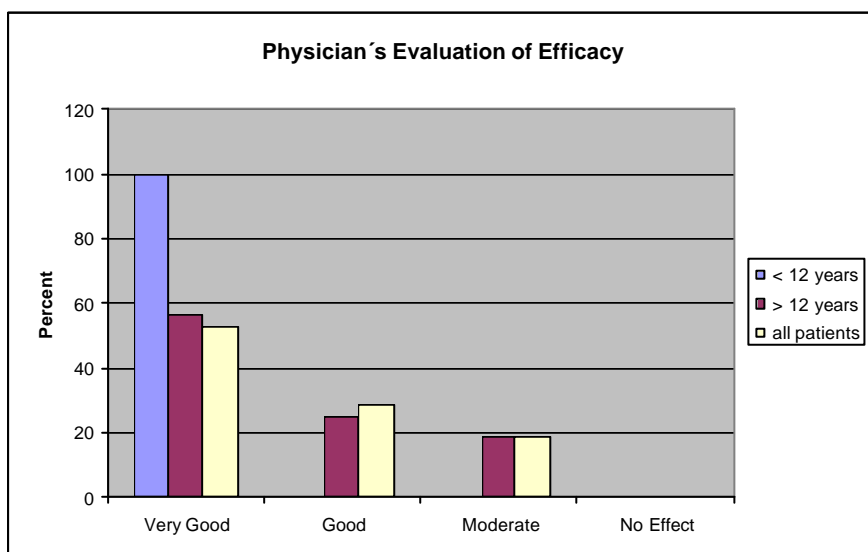
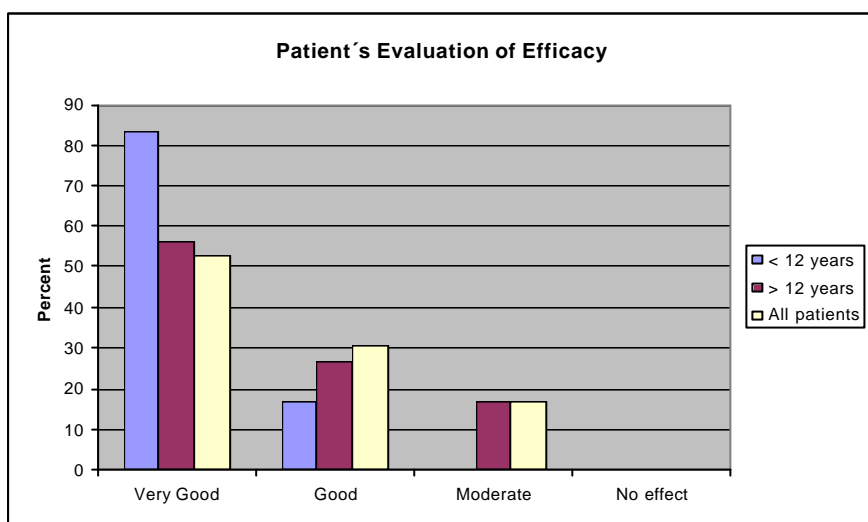


An evaluation of tolerance was submitted by the physicians and patients at the conclusion of the study, whereby an assessment of „very good“, „good“, „moderate“ and „no effect“ could be chosen. 97.8% of patients and 97.3% of physicians rated the tolerance to be „very good“, whilst 2.2% of patients and 2.7% of physicians gave Utilin H 5X a „good“ tolerance rating. No case was assessed as „moderate“ or „no effect“ by patients and physicians alike.



In the children's group under 12 years, the patients rated the tolerance with „very good“ and „good“ and was slightly worse than that of all patients and the over 12 year group, whilst in the younger age group, the assessment of physicians was 100% „good“. No case was assessed as „moderate“ or „no effect“ by physicians and patients alike.

Evaluation of Efficacy								
Patient Group	Patient's evaluation (%)				Physician's evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
< 12 years	83,3	16,7	0	0	100,0	0	0	0
> 12 years	56,4	26,7	16,9	0	56,4	25,0	18,6	0
All patients	52,7	30,4	16,9	0	52,7	28,8	18,5	0



capsules and suppositories. The homoeopathic test preparation, Utilin H 5X, consists exclusively of **Bacillus subtilis 5X** in the 5 decimal potency. The age of the patients varied between 6 and 78 years with an average value of 47.6 years.

Utilin H 5X was used in a very broad application range in accordance with Isopathy, whereby the preferred application was independent of the patient's age. The main indications were bronchitis, lowered resistance and complaints during the post menopause. Accompanying therapies were to be documented in the evaluation form.

The therapy duration of 85.3 days \pm 18.1 days, amongst children (< 12 years) was one half shorter than in the adult group with 151.3 days \pm 77.1 days. In both groups the therapy duration lasted for less than 50 days with three patients. It reveals that among the age group of the children under 12 years, the therapy duration between 76 and 100 days was predominant, whilst among the adults 45% were treated longer than 150 days.

The therapeutic progress was determined by evaluations conducted respectively at the beginning and the end of the therapy. 83.1% of the patients and 81.5% of the physicians rated efficacy as

5.3 Side Effects and Termination of Therapy

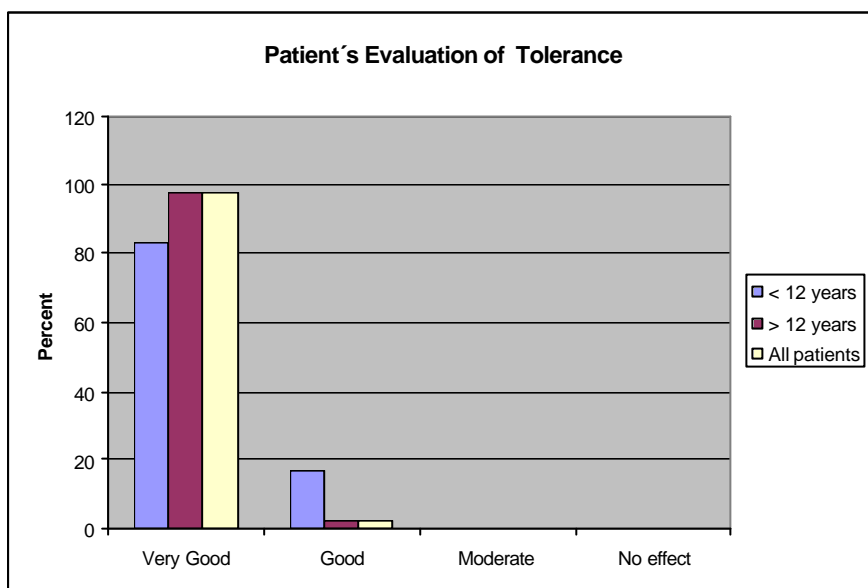
No patient discontinued the therapy with Utilin H 5X and no side effects were reported.

6. Summary

A total number of 184 patients in two medical practices, one specialising in internal medicine and one in general medicine, participated between January 1997 and February 2001 in an application study with the preparation Utilin H 5X in the applications forms of



Evaluation of Tolerance								
Patient Group	Patient's evaluation (%)				Physician's evaluation (%)			
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< 12 years	83,3	16,7	0	0	100,0	0	0	0
> 12 years	97,7	2,3	0	0	97,1	2,9	0	0
All patients	97,8	2,2	0	0	97,3	2,7	0	0



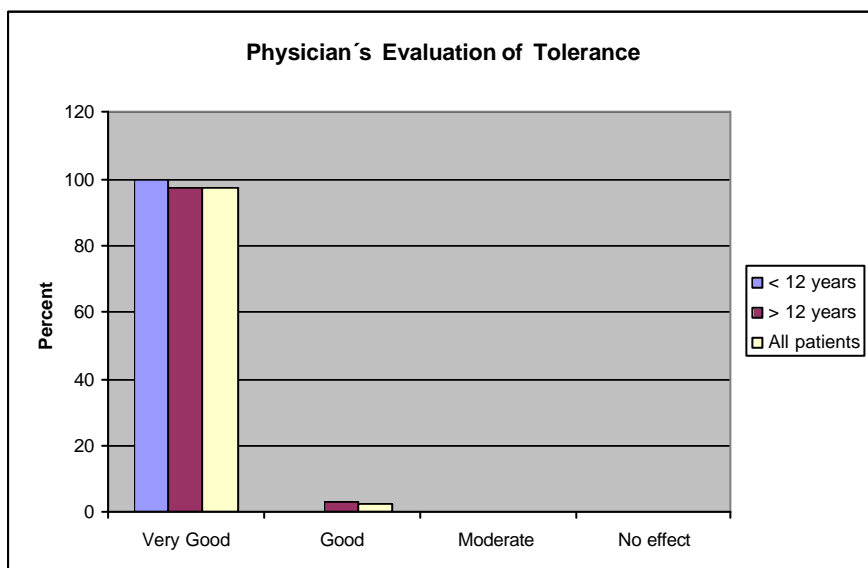
„good“. No therapy was discontinued and no side effects were reported.

Werdorf, 11 July 2001

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„very good“ and „good“. The first-time users rated efficacy with „very good“, which was, according to tendency, better than the assessment of the repeated application users. The evaluation of efficacy by physicians and patients alike was,

according to tendency, better in the group under 12 years, as this age group evaluated exclusively with „very good“ and „good“.

All patients and all physicians rated tolerance to be „very good“ and