Statistical Evaluation

of an Application Study with the Preparation Series

Albicansan

in the administration forms:
capsules, drops, suppositories and injections

by Dr. Reiner Heidl
February 2003

Semmelweis-Institut GmbH
Verlag für experimentelle Onkologie GmbH · 27316 Hoya · Germany

1 Introduction

Between August 1991 and February 2001, a total number of 285 patients in three medical practices, one specialising in internal medicine and two in general medicine, participated in an application study with the preparation series ALBICANSAN in the administration forms of capsules, drops, suppositories and injections. The homoeopathic test preparation, ALBICANSAN, consists (with respect to the different administration forms) of Candida albicans in the 3rd, 4th or 5th decimal potency.

ALBICANSAN D5 drops
10 ml contain: 10 ml Candida albicans D5 dil. in accordance with provision 5a, HAB.
ALBICANSAN D5 dilution for injection
1 ml contains: 1 ml Candida albicans D5 aqueous dilution in accordance with provision 5b and 11, HAB.
ALBICANSAN D4 capsules
1 capsule contains: 330 mg Candida albicans D4 trit. in accordance with provision 6, HAB.
ALBICANSAN D3 suppositories
1 suppository contains: 0.2 g Candida albicans D3 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 the 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, i.e. that all those patients who had at least received one dose of the medicament were included in the study.

2 Participating Patients

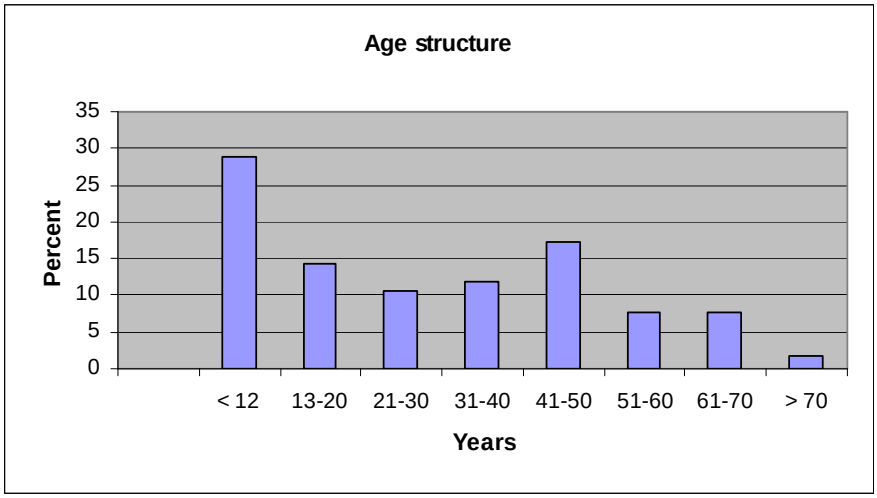
285 patients participated in the study which comprised of 124 males (43.5%) and 161 females (56.5%). The age of the patients varied between 4 and 91 years, with an average age of 30.5 and a standard deviation of 20.6 years. The largest age group was that of patients under 12 years (28.8% of all patients) and the second largest group was the one between 41 and 50 (17.2%). Almost of the same size were the groups between 13 and 20 (14.4%), 21 and 30 (10.5%) and 31 and 40 years (11.9%). 7.7% of all patients were between 51 and 60 and 7.7% between 61 and 70, whilst only 1.8% were over 70 years. Regarding age structure, the males with an average age between 36.0 ± 21.2 were on average 10 years older than the females with 26.3 ± 19.0 years.

Height varied between 102 and 195 cm with an average height of 157.1 ± 23.6 cm and weight was between 15 and 100 kg with an average weight of 56.6 ± 22.0 kg.

2.1 Diagnoses and Secondary Diseases

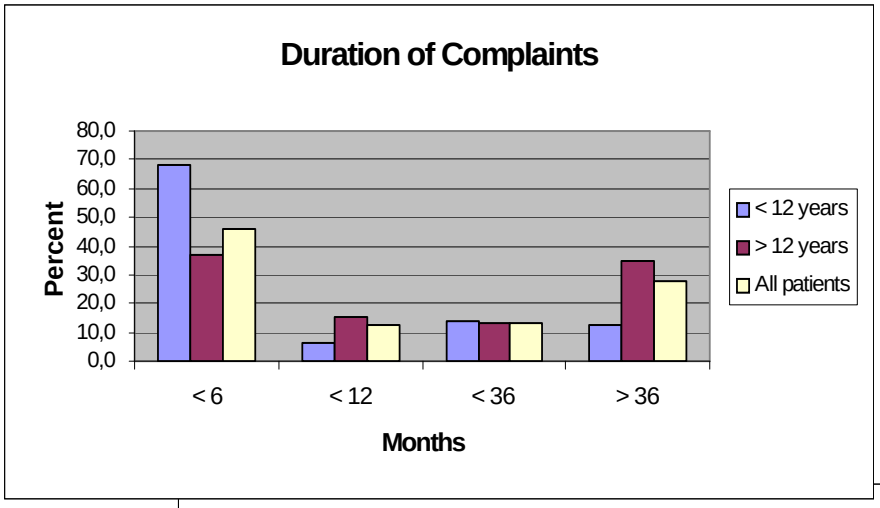
The diagnosis leading to the prescription was to be entered in the study protocol. It showed that ALBICANSAN, according to Isopathy, was used in a very wide application range. The preferred application was independent of the patient's age. The main indications were stomatitis, Perlèche as well as intestinal and skin mykoses. Vaginal mykoses were also indications in the adult age group. A diagnosis was made before the start and end of the therapy. Accompanying therapies were to be documented in the evaluation form.

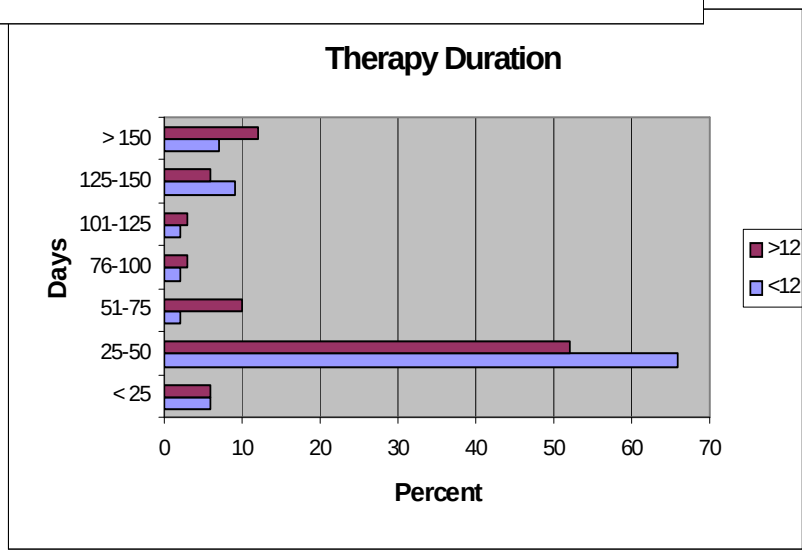
In order to obtain a measure of chronic diseases, the patients were asked in the study protocol how long they had suffered from the disease or complaints. Time frames were given of less than six months, up to one year, up to three years and more than three years.



46% of the patients suffered for less than six months, 12.6% between six and 12 months, 13.3% between one and three years and 28.1% for more than three years. In the patient group over 12 years, 37.1% suffered from acute and 34.5% from chronic complaints. Almost of the same size was the group of patients who suffered for less than 12 months (15.2%) and between 12 and 36 months (13.2%). In the children group under 12 years, acute complaints of less than six months (67.9%) were predominant. Only 6.2% suffered for 12 months, 13.6% up to 36 and 12.3% for more than 36 months.

Duration of Complaints (Months)	Patients < 12 years (%)	Patients > 12 years (%)	Total Patient Population (%)
< 6	67.9	37.1	46.0
<12	6.2	15.2	12.6
< 36	13.6	13.2	13.3
> 36	12.3	34.5	28.1





3. Dosage and Therapy Duration

3.1. Consultation Times, Therapy Duration

According to the nature of an application study, the physicians were not given a preset time limit for the final patient assessment. The final examinations were conducted after a period of 1 to 1100 days, with an average of 72.2 ± 83.2 days.

The therapy duration amongst the children (< 12 years) was on average 59.2 ± 46.5 days and was approx. 25% shorter than in the adult group with 77.5 ± 93.7 days. In both age groups, the therapy duration between 25 and 50 days was predominant, i.e. 67.5% of the patients under 12 and 59.2% of the patients over 12 years.

3.2 Dosage

The dosage was set as follows, according to the patient information leaflet:

ALBICANSAN drops
Oral application: 1 - 8 drops daily before a meal.
Topical application:
2x weekly, 5 - 10 drops on the affected area or in the cubital fossa.

ALBICANSAN injections
2x weekly 1.0 ml i.m., i.v., i.c. or s.c.

ALBICANSAN capsules
1 - 3 capsules daily with some liquid before breakfast or in the evenings at bedtime.

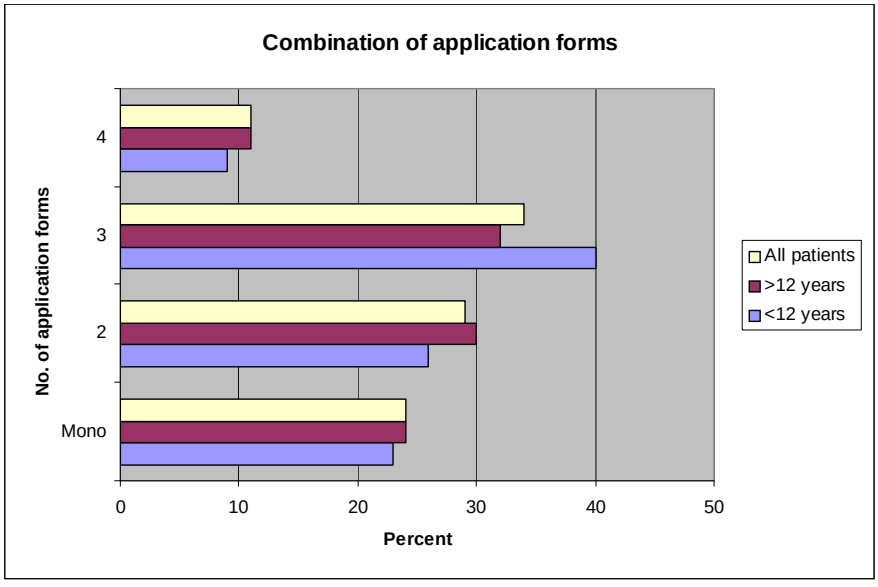
ALBICANSANsuppositories
1x daily, insert 1 suppository rectally at bedtime.

Concerning the administration forms, 178 patients took capsules, 192 patients were treated orally, 68 patients topically (daily), 46 patients topically (weekly), 157 patients with suppositories and 22 patients with injections (weekly). Multiple counts were necessary, if various application forms were combined. Only 24% of the patients were treated with a monotherapy. The most common combination (27.6%) was that of capsules, drops and suppositories. 11.3% of the patients were treated with drops for oral intake, drops for topical application and suppositories. The combination of capsules, drops for oral intake and topical application was used in 7.4% of the patients, whilst only 2.8% were treated with drops for oral intake and topical application. 7.1% were treated with capsules and drops for topical application and 4.2% with a combination of capsules and drops for oral intake. 6.4% were treated with a combination of drops for topical application and suppositories and 4.6% with injections. Other combinations are to be neglected, such as capsules with suppositories (1.4%), capsules with injections (0.7%), drops for oral intake with suppositories (1.8%) and suppositories with injections (0.7%). No exact doses were recorded for two patients of the injection group. There was no significant difference in the dosages in the age groups under 12 and over 12 years and the extent of the combination of the application forms.

Total Population			
	medium dose	minimum dose	maxiumum dose
Capsules	2.7 ± 0.5	1	3
Drops für oral intake	9.0 ± 5.4	3	30
Drops for topical application daily	6.0 ± 3.5	2	20
Drops for topical application weekly	20.3 ± 11.0	8	48
Suppositories	1.1 ± 0.3	1	3
Injection ml weekly	1.7 ± 0.5	1	2

All patients under 12 years				
	medium dose	minimum dose	maxiumum dose	patients
Capsules	2.5 ± 0.6	1	3	58
Drops für oral intake	6.8 ± 2.8	3	20	73
Drops for topical application daily	6.9 ± 4.6	2	20	28
Drops for topical application weekly	0	0	0	0
Suppositories	1	1	1	38
Injection ml weekly	2	2	2	1

All patients over 12 years				
	medium dose	minimum dose	maxiumum dose	patients
Capsules	2.8 ± 0.4	2	3	120
Drops für oral intake	10.3± 6.1	5	30	119
Drops for topical application daily	5.3 ± 2.2	2	10	40
Drops for topical application weekly	20.3 ± 11.0	8	48	46
Suppositories	1.2 ± 0.4	1	3	119
Injection ml weekly	1.7 ± 0.4	1	2	19

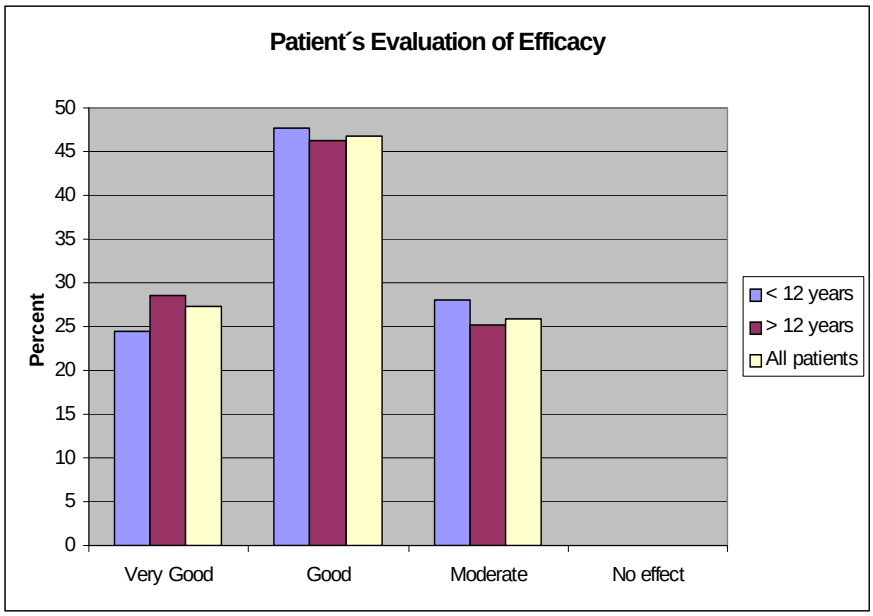


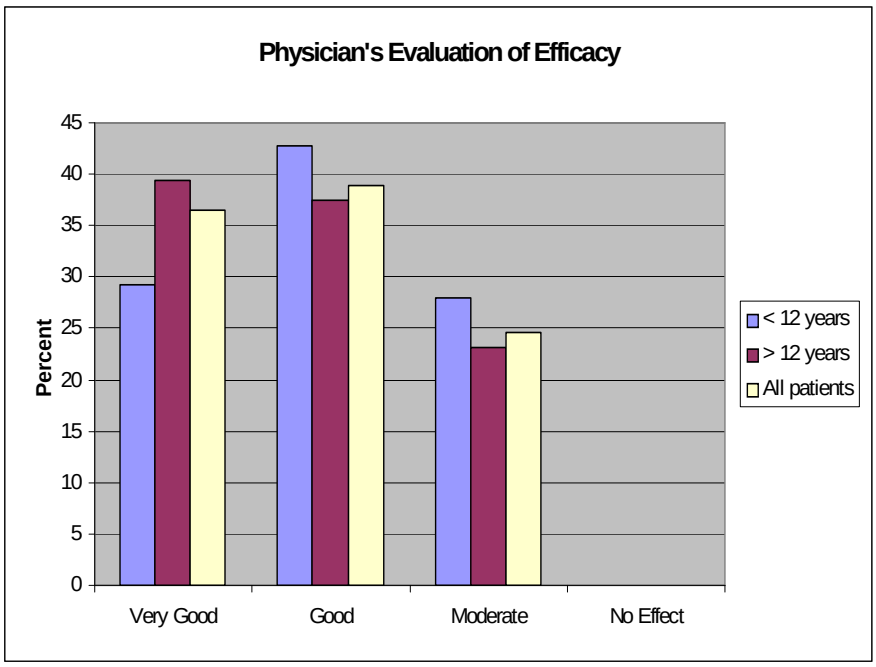
4 Efficacy and tolerance

4.1 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 compliance with „very good“, „good“, „moderate“ or „non-compliant“. The evaluation of efficacy showed that 74.1% of the patients assessed efficacy with „very good“ and „good“, whilst 25.9% assessed efficacy with „moderate“. No patient assessed efficacy with „no effect“. The results of the physicians' evaluation for efficacy were almost identical to that

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	24,4	47,6	28,0	0	29,3	42,7	28,0	0
> 12 years	28,6	46,3	25,1	0	39,4	37,4	23,2	0
All patients	27,4	46,7	25,9	0	36,5	38,9	24,6	0





of the patients. In 75.4% of the cases physicians assessed efficacy with „very good“ and „good“ and 24.6% with „moderate“. In comparison with the adult and the children groups under 12 years, according to tendency, the evaluation of the physicians and patients shifted to „good“.

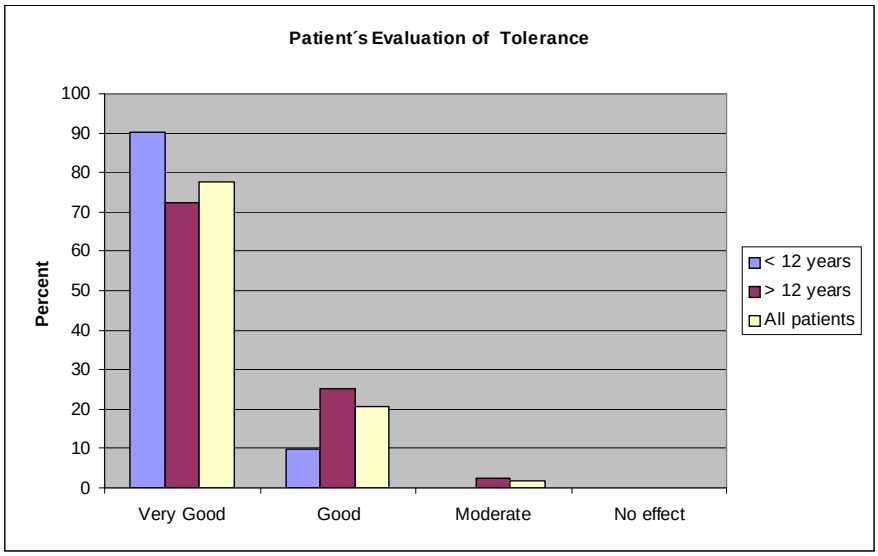
Compliance (N = 280) was assessed by the physicians to be „very good“ for 131 patients, „good“ for 109 patients, „moderate“ for 37 and „non-compliant“ for 3 patients. Hence 84.2% of all patients participating in the study were given a „good“ or „very good“ compliance rating.

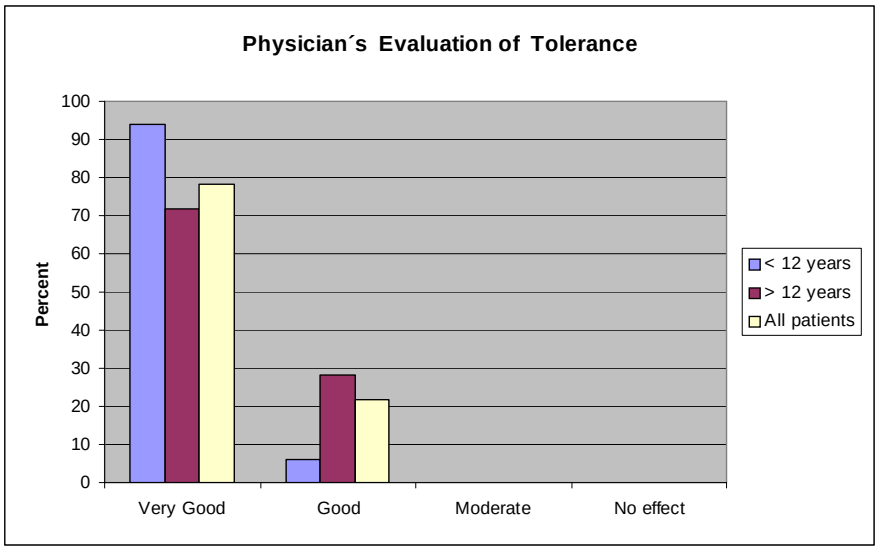
4.2 Evaluation of Tolerance by Physician and Patient

At the conclusion of the study, an evaluation of tolerance was submitted by the physicians and patients whereby an assessment of „very good“, „good“, „moderate“ and „no effect“ could be chosen. 77.5% of patients and 78.2% of physicians rated tolerance to be „very good“, whilst 20.7% of patients and 21.8% of physicians gave ALBICANSAN a „good“ tolerance rating. 1,8% of the patients rated with „moderate“ and neither patient nor physician with „no effect“.

In the age group under 12 years, patients and physicians rated tolerance to be approximately 20% better with regard to the „very good“ assessment. With regard to quality and quantity, the assessments of physicians and patients alike were of equal value in total.

Evaluation of Tolerance								
Patient Group	Patient´s evaluation (%)				Physician´s evaluation (%)			
	Very good	Good	Moderate	No effect	Very good	Good	Moderate	No effect
< 12 years	90,2	9,8	0	0	93,9	6,1	0	0
> 12 years	72,4	25,1	2,5	0	71,9	28,1	0	0
All patients	77,5	20,7	1,8	0	78,2	21,8	0	0





4.3 Side Effects and Termination of Therapy

No therapy with ALBICANSAN was discontinued and no side effects were reported.

5. Summary

Between August 1991 and February 2001, a total number of 285 patients in three medical practices (two specialising in general medicine and one in internal medicine) participated in an application study with the preparation series ALBICANSAN in various administration forms: capsules, drops, suppositories and injection. The homoeopathic test preparation, ALBICANSAN, consists (with respect to the different administration forms) of Candida albicans in the 3rd, 4th or 5th decimal potency.

The age of the patients varied between four and 91 years with an average age of 30.5 years.

ALBICANSAN, according to Isopathy, was mainly used in a very wide application range, independent from the patients' age. The main indications were stomatitis, Perlèche and intestinal and skin mycoses. Vaginal mycoses were also indications in the adult group. Accompanying therapies were to be documented in the evaluation form.

46% of the patients suffered for less than six months. The second largest group (28.1%) suffered for more than 36 months. In the age group under 12 years, acute complaints of less than six months were predominant with 67.9% of the patients. Only 6.2% suffered for 12 months, whilst 13.6% suffered between 12 and 36 months and 12.3% for more than 36 months.

Amongst the children (< 12 years) the therapy lasted on average 59.2 ± 46.5 days and was approximately 25% shorter than in the adult group with 77.5 + 93.7 days. The therapy duration for both age groups between 25 and 50 days was predominant in 67.5% of the patients under 12 and in 59.2% of the patients over 12 years.

Concerning the administration forms, 178 patients took capsules, 192 patients were treated orally, 68 patients topically (daily), 46 patients topically (weekly), 157 patients with suppositories and 22 patients with injections (weekly). Multiple counts were necessary, if various application forms were combined. Only 24% of the patients were treated with a monotherapy with only one administrattion form. The most common combination (27.6%) was that of capsules, drops and suppositories.

There was no significant difference between the age groups under 12 and over 12 years with respect to the dosage and the frequency of combinations of the application forms.

The therapeutic progress was determined by evaluations conducted at the beginning and the end of the therapy. In both age groups, there was no difference regarding the extent of combinations of the administration forms.

The evaluation of efficacy showed that 74.1% of the patients assessed efficacy with „very good“ and „good“, whilst 25.9% assessed with „moderate“. No patient assessed efficacy with „no effect“. The results of the physicians' evaluation for efficacy were almost identical to that of the patients. In 75.4% of the cases, physicians assessed efficacy with „very good“ and „good“ and 24.6% with „moderate“. Comparing the adult and children groups under 12 years, according to tendency, the evaluation of the physicians and patients shifted to „good“.

Compliance (N = 280) was assessed by the physicians to be „very good“ for 131 patients, „good“ for 109 patients, „moderate“ for 37 and „non-compliant“ for 3 patients, hence 84.2% of all patients participating in the study were given a „good“ or „very good“ compliance rating.

77.5% of patients and 78.2% of physicians rated tolerance to be „very good“ whilst 20.7% of patients and 21.8% of physicians gave ALBICANSAN a „good“ tolerance rating. 1.8% of the patients rated with „moderate“ and neither patient nor physician with „no effect“. In the age group under 12 years, patients and physicians rated tolerance to be approximately 20% better with regard to the assessment „very good“. Concerning quality and quantity, the assessments of physicians and patients alike were overall of equal value. No therapy with ALBICANSAN was discontinued and no side effects were reproted.

Werdorf, 7 February 2003

Dr. Reiner Heidl