



**THE  
THERAPEUTICS  
OF THYMUS-PEPTIDES  
IN THE PREVENTION  
OF HAIR LOSS**

**This manual contains a collection of clinical research performed in Germany and articles published in various health publications across North America demonstrating the therapeutics of thymus-peptides in the prevention of hair loss due to radiation, chemicals, chemotherapy, or different forms of alopecia, and help you to regrow new, strong, healthy hair which is permanent in both adult sexes.**

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# **KLINISCHE DOKUMENTATION UND ERFAHRUNGSBERICHTE**

**CLINICAL DOCUMENTATION**



## Preface

It is a pleasure for us to provide you the following summary report of the German Cancer Research Center (DKFZ) Heidelberg, department of medical and biological informatics entitled " Alopecia during treatment with different chemotherapeutical regimen" written by Professor Dr. Claus O. Köhler. This is to our knowledge the first one which deals with the result of various clinical studies, which are concerned with hair loss, the most important symptom occurring during oncological treatment and an additional psychological burden of the individual patient. Please ask for detailed results of individual studies on which the following summary is based on.

As introductory remarks we would like to point out:

- as confirmation of already known data about the therapeutical potential of Thymu-Skin in previous studies an investigation has been performed at the Medical University of Hannover in terms of a randomly organized double-blind study. Due to a large number of articles published about alopecia and chemotherapy no further double-blind study is necessary.
- Especially the results obtained by the University clinic in Munich seem to be important. At this study none of the patient undergoing a mild or moderate chemotherapy developed an alopecia totalis during accompanying treatment with Thymu-Skin.

Results obtained by oncological studies with other patients with other types of hair loss could be confirmed in various clinical trials. The explanation of the mode of action of the biological product Thymu-Skin is subject of various clinical trials which are still going on.

In each case it can be summarized, that Thymu-Skin could improve in the last years in a lot of patients the psychological condition and could stabilize and improve the feeling of their own value.

Without support of a lot of famous physicians of the universities of Heidelberg, Münster-Osnabrück, Hannover, München, Ludwig-Boltzmann-Institut Vienna and the dermatological clinic in Darmstadt this would not have been possible. Furthermore we would like to thank for the scientific support by the German Cancer Research Center (DKFZ) in Heidelberg and Ministry of Science and Technology in Bonn-Bad Godesberg.

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## Alopecia during treatment with different chemotherapeutical regimen

C.O.Köhler

### 1. Introduction

Pharmaceutical substances used for treatment of tumors or their metastases are cytotoxic and affect more or less the cutis vera with the hair follicles. Under this therapy a (mostly reversible) loss of hair from the scalp occurs in most of the cases.

Loss of hair especially for female patients is an additional stress factor which does not support but hinders the success of treatment. The defenses form of the body is diminished by the stress of hair loss. Concerning an effective therapy the patient should be spared the additional stress of hair loss. In a preliminary examination it has been found that there is no correlation between the results and sex, so in the following we do not distinguish between male and female patients. Besides that cases of mamary carcinoma are, of course, always female patients.

### 2. Study group

In studies at different universities and hospitals patients with malignant tumors undergoing a chemotherapy have used Thymu Skin (shampoo and lotion) for hair shampooing and treatment. The results of these studies are analysed in this brochure. In this summary the prevention of hair loss during various cytotoxic treatment regimen should be analysed. In addition, it could be examined, if even the tumor diagnosis and/or the age of the patient has any effect on the prevention of hair loss.

In none of the studies the number of patients was sufficient to perform the study. So patients from all studies with the predominantly applied cytotoxic regimen have to be combined in order to obtain a sufficient number of subjects. So 144 patients treated with 5-fluorouracil (mono or combined therapy), and 107 patients treated with adriamycin (mono or combined therapy, too) have been combined. These two chemotherapeutic drugs only were used in all studies often enough to include them in a trial on the influence of age and tumor diagnosis. There were no simultaneous treatment with 5-fluorouracil and adriamycin; few cases with simultaneous treatment were excluded from the study.

The tables 1 and 2 as well as figure 1 and 2 are presenting the study group.

Table 1: Patients treated with adriamycin

Age (years)	Malignancy					Total
	Stomach	Bronchus	Hodgkin	Kidney	Pancreas	
≤ 50	36	1	2	1	1	41
51-60	30	0	0	0	5	35
> 60	30	0	0	1	0	31
Total	96	1	2	2	6	107

Table 2: Patients treated with 5-fluorouracil

Age (years)	Malignancy					Total
	Stomach	Bronchus	Hodgkin	Kidney	Pancreas	
≤ 50	19	9	9	6	7	50
51-60	9	14	6	2	9	40
> 60	16	10	8	8	12	54
Total	44	33	23	16	28	144

As expected, these tables and the respective figures show no interrelation between age and diagnosis. Therefore it seems to be most interesting to analyse the effect of age and tumor diagnosis.

### 3. Results

The change in WHO score of hair loss during chemotherapy and during additional treatment with Thymu Skin has been analysed. The WHO score has 4 degrees: 1 - no change; 2 - deterioration by 1 level; 3 - deterioration by 2 levels, 4 - deterioration by 4 levels. In one case an improvement by 1 level occurred; this case has been classified to the group "no change".

#### 3.1. Summary of results

In figure 3 the results are given without consideration of age and tumor diagnosis. It becomes very clearly that in subjects treated with 5-fluorouracil a stronger prevention of hair loss occurred than in patients treated with adriamycin. The difference is statistically significant ( $p < 0.05$ ). On the other hand it must be mentioned that also in the group of patients treated with adriamycin there was a relatively high number of cases who showed no change in WHO scores or a deterioration by only 1 level (22 cases=20.7%). This would be impossible without application of Thymu- Skin.

#### 3.2 Age dependency

The relation between prevention of hair loss and age of the patient is shown in figure 4. In the group of patients treated with 5-fluorouracil and in the group of patients treated with adriamycin the elder patients showed a relatively better prevention of hair loss than the younger ones. By the combination of these results this statement became statistically significant.

Analysing a four-field-contingency table with the patients to age of 60 and those over 60 and the changes in WHO score 0-1 and 2-3 it can be found in 5-Fu treated subjects (Table 3) that 68,5% of

the older subjects but only 58,9% of the younger ones are in the group without or with only slight hair loss (not statistically significant). In the patients treated with adriamycin the ratio is 48.4 and 10.6% (statistically significant).

Table 3: Prevention of hair loss by Thymu Skin in relation to chemotherapy and age

WHO score of hair loss (changes)	5-Fluorouracil		Adriamycin	
	≤ 60	> 60	≤ 60	> 60
0 and 1	53	37	7	15
2 and 3	47	17	59	16
Total	90	54	66	31

### 3.3 Type of malignancy

First, it seems to be improbable that prevention of hair loss by application of Thymu Skin during a chemotherapy depends not only on the cytotoxic treatment but also on the tumor diagnosis, but nevertheless our patients show such a correlation. 89.7% of the patients treated with adriamycin were patients with stomach carcinoma. So no further examination can be performed (table 4 and figure 5).

Table 4: Prevention of hair loss by Thymu Skin in relation to the diagnosis of the malignant disease in patients treated with adriamycin

WHO score of hair loss (changes)	Malignancy	
	Stomach	other carcinoma
no change	2	1
1 level changed	19	0
2 level changed	42	4
3 level changed	33	6
Total	90	54