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CLINICAL EXAMINATION OF THE EFFICACY OF PREPARATIONS DOCTOR MICHAEL IN THE TREATMENT OF CASES OF PSORIASIS WITH DIFFERRING SEVERITY

**REPORT** 

MOSCOW

2002

The disease of psoriasis has posed a serious problem concerning health care and social issues for long periods of time partly because the disease affects 1 to 3% of the world's population and partly because the treatment results are extremely modest.

The international and national experience supports that the preparations currently used for the treatment of psoriasis are not always effective, furthermore the treatment is of considerable length and frequently causes side effects. With view to the above mentioned facts, the development and introduction of a product line of non-hormonal basis suitable for the external treatment of psoriasis is exceptionally important since the prolonged application of steroid preparations causes a number of unwanted local and systemic effects in patients.

The clinical examination of Doctor Michael's product line was carried out at the Department of Dermatology and Venereology of the Paediatric Clinic of the Russian State Medical University in order to assess the efficacy of the preparations in the treatment of patients of deferring age and disease severity groups as well as to assess the potential side effects.

30 patients (15 children and 15 adults) participated in the studies, who were selected from among the patients treated at the Department of Dermato-allergology of the Russian Paediatric Hospital Clinic (Moscow) and at the 4<sup>th</sup> Department of Dermatology of the 52<sup>th</sup> Moscow City Hospital Clinic. The clinical studies were carried out by the staff of physicians of the Department of Dermatology and Venereology of the Paediatric Clinic of the Russian State Medical University and the doctors of the hospital department described above.

### The Goal of the Studies

To assess the efficacy of Doctor Michael's product line in the treatment of patients of differing age and disease severity groups.

### <u>Method</u>

Clinical.

### Composition of Doctor Michael's Product Line

Doctor Michael's product line offers three different preparations: a gel, an ointment and a conditioner.

Table 1. Composition of the constituents of the Doctor Michael product line:

		Doctor Michael's Skin P	rotective	Doctor Michael's Skin Cor	aitioner
		Ointment (orang	e)		
Water	69.9 %	Wheat germ oil	11.0 %	Olive oil	20.0 %
Solution of coal tar	2,0 %	Sweat almond oil	9.0 %		
		Evening primose oil		Sesame seed oil	18.0 %
Sodium lauryl ester	10.0 %	Vaseline			
sulphate		Zinc hyperoxide	3.0 %	Mineral oil	18.0 %
Coco-amido-dipropyl-	4.0 %	<del>                                     </del>			
betaine		Oil of apricot stone	15.0 %	Beeswax	18.0 %
Triethanol-amine-lauryl-	6.0 %	<u> </u>	<b>[</b>	ļ	
sulphate		Mineral oil	3.0 %	Sunflower seed oil	10.0 %
Organic acids	1.0 %	Carragene		[	
Fruit acids	<del></del>	Carrot oil	3.0 %	Emu oil	2.0 %
		Fruit acids		j	
Coconut oil- diethanol-	3.0 %	Lavender oil	6.5 %	Lavender oil	2.0 %
amide		Eucalyptus oil	[		
Carbolol	0.8 %	Tea tree oil	5.0 %	Eucalyptus oil	2.0 %
Trietanol-amine	<del> </del>	Bergamot oil	İ	1	
Imidazolodinyl-	<del></del>	Sandalwood oil	12.0 %	Rosemary oil	2.0 %
carbamide	į	Patchouli oil			
Methyl-parabene	0.2 %	Pine oil	2.0 %	Vitamin E	3.8 %
Tetrasodium -EDTA	0.2 %	Pepperoni oil		Chickweed extract	2.0 %
		Orange oil	2.0%		4,7
Total	100.0 %	Neroli oil		Calendula oil	2.0 %
<del></del>		Calendula oil	5.0 %		2.7.7
		Olibanum oil		Disolydinyl- carbamide	0.2 %
		Citronella oil	2.5 %		
		Chickweed extract		Total	100.0 %
		Matricaria extract	2.5 %	· '	
		bay oil	2.0%		
		Disolydinyl-carbamide	2.5 %		
		Total	100.0 %		

### Application and Doses of Doctor Michael's Preparations

All the patients of the different age groups were treated precisely according to the product description, in line with the method developed by Doctor Michael twice daily: in the morning and in the evening.

During the course of the treatment, the patients were given anti-histamine preparation, and in addition, in the case of children, a sedative (anxiolythic) mixture was also applied.

No local steroid preparations were used during the treatment.

### **Selection of Patients**

30 patients with psoriasis of different severity were included in the study with an age range of 9 to 60 years. As far as children are concerned, 3 girls and 12 boys participated, while the ratio for adults was 5 women and 10 men.

Table 2. Distribution of patients broken down by sex and age

Age groups	Age of the Patients (years)	Girls	Boys	Total
	0 - 5	<u>-</u>	_	-
	5 – 10	2	2	4
<u> </u>	10 – 16	1	10	11
Children	Children total	3	12	15
	Age of the patients (years)	Women	Men	Total
· · · · · · · · · · · · · · · · · · ·	16 – 20	2	1	3
	20 – 30	2	3	5
32 <b>6</b> 1	30 – 40	-	3	3
Adults	40 - 50	1		1
₹	50 - 60	<del>-</del>	3	3
	Total of adults	5	10	15
	Total of patients	8	22	30

Before starting the treatment, laboratory and physical examinations were completed on each patients with verified diagnosis of psoriasis. The duration of disease persistence ranged within 4 months and 21 years and the duration of the latest exacerbation was between 1 week and 29 months.

### Description of the Patient Groups

The entire patient group (30 patients) was divided into three groups on the basis of the PASI-index values calculated during the preliminary tests according to the severity of the skin lesions.

Table 3. Distribution of Patients according to the Severity of the Disease (based on the PASI-index)

Patient Groups	Severity of the Dise	ase	Average Values of the	Number of Patients
	(PASI)		PASI-index (control	
	<b>{</b>		tests)	{ 
I	mild	0-20	9.3	12
П	moderately severe	20-50	37.6	9
Ш	severe	> 50	63.3	9
	<u></u>	· •·	Total:	30

The first group consisted of 12 patients (6 children and 6 adults) who exhibited mild skin lesions (PASI < 20), the average PASI-value of this group was 9.3.

The second group consisted of 9 patients (4 children and 5 adults) who exhibited moderately severe skin lesions. The average PASI-value of this group was 37.6.

The third group consisted of 5 adults and 4 children who exhibited a severe form of the disease (PASI > 20). The average PASI-value of this group was 63.3.

The high frequency of the severe skin lesions among children is due to the fact that generally patients with more severe lesions, who show pronounced symptoms of exacerbation at the time of hospitalisation, are referred to the Department of Dermato-allergology by doctors from all over the Russian Federation.

In group 1, in the case of patients with mild disease, the clinical picture of psoriasis was characterised by localised skin lesions. In addition, in the foci of the lesions, moderately

pronounced objective and subjective symptoms were observed. In cases of two patients out of the twelve, no itching was observed.

In group 2, in the case of patients with a moderate from of the disease, we noted more intense itching as the dominant symptom, in comparison with group 1. There were extensive skin lesions and these appeared on the front and back part of the skin of the trunk and on the upper and lower extremities. A moderate from of erythema and oedema was observed on the patients, furthermore, the fusion of the papules into plaques was observed. A more definitive inflammatory reaction and significant desquamation were also observed among the patients of this group.

In group 3, in the case of patients with a severe form of the disease, the disease manifested on the facial skin and on the lateral sides of the front and back parts of the neck and the trunk. In addition, the disease caused partial erythrodermia on the upper and lower extremities.

### **Evaluation of the Clinical Symptoms**

The so called PASI-index was used to objectively define the severity of the disease and the efficacy of the treatment. This index characterises the area of the skin lesions and the combined severity of objective (erythema, desquamation and infiltration) and subjective (itching) symptoms. In the case of maximal extension and pronounced objective and subjective symptoms, the PASI-index totals 96 and, in the case of complete absence of symptoms the index equals 0 (PASI=0).

With the help of the PASI-index, we were able to determine the severity of the process affecting the skin for each single patient.

 $0 \le PASI \le 20$  mild process

 $30 \le PASI \le 50$  moderately severe process

50 < PASI - severe process

The determination of the PASI-index was carried out with the help of a special computer programme.

In the case of each patient, a special, unique record was also created to accompany the usual standard documentation, in which the PASI-index values before and after the application of the Doctor Michael preparations were recorded. Thus we were able to observe the dynamics of the process affecting the skin.

### Result of the Experiment

The efficacy of the treatment used was evaluated as follows:

clinical remission;

significant improvement;

improvement;

lack of change;

deterioration.

The obtained results were recorded in a summary table and were also presented in a graphic form showing the changes of the PASI-index on days 3, 7, 14, and 21 counted from the start of the experiment.

The horizontal axis indicates duration of the treatment in days, and the vertical axis indicates the corresponding PASI-index values.

The individual records also show how much the patients tolerated the application of the given preparation-group, the negative side-effects if any and, noteworthy remarks on each patient were also recorded after the termination of the treatment.

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### Dynamics of changes in the PASI index

Days of the control examination moderately severe severe

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In the case of 8 patients out of the 9 patients of group 3 (disease with severe a course), on the 3rd day of the treatment itching and desquamation decreased significantly in the foci. (We no other choice but to exclude 1 patient from the study due to the development of contact dermatitis.) At the same time, the overall PASI-value only slightly (13%) decreased compared to the initial value. By day 7 of the treatment, significant improvements were observed in the general condition of 4 patients with significant alleviation of itching accompanied by the disappearance of erythema and alleviation of desquamation and infiltration. (The overall PASI-value decreased by 41% compared to the initial value.) On day 14, the decrease of the PASI-index exceeded 74% compared to the initial value. In the case of two patients, itching and desquamation ceased completely. By day 21 of the experiment, significant improvement was observed in the case of four patients, improvement was observed in the case of two patients and clinical remission was observed in one case. (The PASI-index decreased from 64.2 to 0.4). We observed deterioration in the case of one single patient (record no. 25). In the case of a fourteen years old boy, on days 6-7 of the treatment, the application of Doctor Michael's product-family induced contact dermatitis as a result of individual sensibility to the components of the preparation. The treatment of this patient was terminated in spite of a positive effect on the primary disease.

As far as group 2 representing patients with moderately severe cases is concerned, in the case of 7 patients out of 9 patients, itching and desquamation significantly dropped. (2 patients were excluded from the programme.) Starting from day 3 of the treatment, the improvement proved to be stable in 4 patients out of 5 as it manifested in the decrease of intensity of itching and desquamation until day 14, when the symptoms completely disappeared. By day 21 of the treatment, the condition of two patients improved significantly, 1 patient's condition improved and clinical remission was observed in the case of 4 patients. (The average PASI-value in the case of this group decreased from 37.6 to 4.1.) In the case of one patient (record no. 17) the process affecting the skin worsened due to individual sensibility to the preparation. After the termination of the treatment, the condition of the patient returned to normal. We were forced to exclude another patient from the programme, since the psoriatic process worsened due to the consumption of alcohol.

With reference to group 1, which was made up of patients with a mild form of the disease, a definite improvement was observed in the condition of 10 patients out of 12 as early as on the starting days of treatment. By day 14 of the experiment, itching (5 patients) as well

as the inflammatory symptoms (erythema/1 patient, oedema/2 patients) ceased completely. By day 21 of the experiment, clinical remission was observed in the case of each member of the group. (The PASI-index decreased by 91% compared to the initial value.) One patient (record no. 4) of the group developed contact dermatitis during the treatment, so this patient was excluded from the study. Another patient (record no. 9) had used the whole amount of ointment within 2 days, which led to the deterioration of the psoriatic process, consequently this patient was also excluded from the study.

To summarise the experience concerning the application of Doctor Michael's preparation, we observed clinical remissions during the treatment of psoriasis in adults and in children (table 5). This meant a complete disappearance of rash in 5 patients, significant improvement in 16 patients and improvement in 8 patients.

In case of two patients, the treatment proved to be effective but the patients were excluded from the study due to the development of side effects. In one case, the patient did not observe the applicable rules (alcohol consumption) and, as a result, this patient was excluded. In two cases, the disease process became generalised, which was induced by individual sensibility in one patient and by overdosing of the preparation (ointment) in the case of the other patient. Based on the above, during the preparation of the report we did not include and consider the results of the treatments of five patients.

Table 5. The Clinical Efficacy of Doctor Michael Preparations

Results of the treatment		Degree of Severi	ty of the Disease	
	Mild (n = 12)	Moderate (n = 9)	Severe (n = 9)	Total
Clinical remission	10	4	2	16
Significant improvement	-	2	4	6
Improvement	-	1	2	3
No effect	1	1	1	3
Deterioration	1	1	-	2
Total	12	9	9	30

### **Summary**

- This treatment method is highly effective and, in terms of efficacy, it is comparable to the generally used therapeutic regimen, which are based on the application steroid ointments with fluoride content.
- Doctor Michael's preparations do not have severe side effects, they are user-friendly, they do not have an unpleasant smell, they do not stain the underwear and can successfully be applied in the case of outpatients as well.
- 3. Parallel application cannot exceed 30 percent of the total body surface of the patient.

### A. A. Thihomirov, assistant

Head of the study completed at the Department of Dermato-allergology of the Russian Paediatric Hospital Clinic

### A. A. Kubilinsky, assistant

Head of the study completed at the 4<sup>th</sup> Department of Dermatology of the 52<sup>th</sup> Moscow City Hospital Clinic

Evaluation of the main symptoms in the case of patients with a mild form of psoriasis

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### Dynamics of the main symptoms in the case of patients with a mild form of psoriasis

Intensity Itching Erythema Desquamation Desquamation

of patients with a moderately severe form of psoriasis Evolution of the main symptoms in the case

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			Control	l examin	inatio	_				ontro	Control examination	ination				5	Control	examination	rafio	۱.
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13 .ecc		∞	δ.	-	0	0	000	e Itching	~	7	0	0		S o Itching	50	16	12	<b>∞</b>	4	0
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	Desquamation	12	4	0	0	0		Desquamation	4	14	0	0		N T	esquamation	13	13	11	9	
d-	Infiltration	13	13	3	7	0	d	Infiltration	14	14	7	2		E Infiltration	ation	2	12	12	4	_
prd	Intensity	7	14	4	14	•	þj	Intensity	17	<i>L</i> 1	<i>L</i> 1			न् Intensity	(j.	2	2	10	7	•
14 .ecc	Itching	9	_	0	0	•	ကခ	Itching	00	∞	16			SO Itching		91	91		4	2
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	Desquamation	9	4	0	0	1		Desquamation	<b>∞</b>	∞	œ			N T	esquamation	13	12	=	9	∞
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I 2 .ecc		4		0	0	· <del>· · · · ·</del>	000	e Itching	11	11	4	0	0	S Itching	ne.	•	∞	9	4	0
nt i	Erythema	6	6	9	2	•		Erythema	12	12	<b>∞</b>	٣	0	Erythema	ma	00	00	9	9	4
	Desquamation	12	m	0	0	1		Desquamation	6	6	_	4	0	N <del>D</del>	esquamation	90	∞	∞	•	$\overline{}$
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14	16	12	13	12	10	91	12	13	12	6	ø	<b>00</b>	90	8
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	6	[.0]	1		_	07	, OI	<u>,                                    </u>	_	rd	17	nt r	atie	d

# Median values of the main symptoms in the case of patients with a moderately severe form of psoriasis

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	0	0	0	0	0	4	4	1,1
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0	 14	9	0	0	
0	 9	6	7	4	
	 13	13	11	9	]
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3,3

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### Dynamics of the main symptoms in the case of patients with a moderately severe form of psoriasis

Intensity Itching Erythema Desquamation Desquamation

## Median values of the main symptoms in the case of patients with a severe form of psoriasis

	٠	Control		examination	=			)	ontro	Control examination	inatio	_			C	Control	examination	nation	_
	0	6	-	7	21			•	8	7	7	71			•	6	7	7	77
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Itching	15	13	9	2	0	1000	o Itching	16	00	δ.			0		12	7	4	0	0
Erythema	15	13	9	_	_		Erythema	91	10	9			n it Lo		16	91	12	4	<del>,</del>
	16	6	3		0		Desquamation	16	9	4			ıticı M		91	91	12	00	_
Infiltration	13	10	5	2	0	ed	Infiltration	16	6	9		,	ed	Infiltration	16	16	12	4	_
												_							
Intensity	18	18	81	18	2	p,ı	Intensity	21	21	21	21	12	þı	Intensity	12	12	12	91	٥
Itching	9	2	0	0	0		Itching	6	00	7	4	0	0		6	Ò	9	<u></u>	0
Erythema	12	12	6	5	1	n in	Erythema	16	œ	<b>∞</b>	00	ω	n tr 2.0		12	12	∞	9	4
Desquamation	16	9	٣	0	0		Desquamation	16	œ	4	0	0	tiet M		12	12	6	9	~
Infiltration	14	14	14	9	2	8d	Infiltration	14	14	=	80	9	ed	Infiltration	6	6	0	Ŷ	m
								!											
Intensity	18	18	81	18	12	þı	Intensity	14	14	11	4	4	ьı	Intensity	15	15	12	∞	S
Itching	13	12	δ.	ς.	-	တခ	o Itching	91	=	œ	-	0	009	Itching	12	6	9	۳	0
Erythema	16	16	91	<b>∞</b>	4		Erythema	12	12	91	4	m	nt tr 10,2	Erythema	6	6	9	9	7
Desquamation	16	∞	9	_	0		Pesquamation	91	91	12	4	_			12	12	6	9	7
Infiltration	16	16	91	10	4	3d	Infiltration	12	Ξ	01	3	۳	ed .	Infiltration	.12	12	12	•	0

### case of patients with a severe form of psoriasis Evaluation of the main symptoms in the

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Infi	2	14	16	4	12	91	6	12	
	13	4	91	14	12	16	6	2	13,3
				<u> </u>	<u> </u>	L	·		
	0	0	0	0	1	1	3	2	
tion	1	0	1	0	4	8	9	9	3,3
uama	3	3	9	4	12	12	9	6	
Desq	6	9	8	8	16	16	12	12	10,81
	16	91	16	16	16	91	12	12	
	-	1	4	٤	٤	1	4	2	2,4
13	1	5	8	8	4	4	6	9	5,3
Erythema	- 9	6	16	8	10	12	8	9	9,4
Œ	13	12	16	8	12	16	12	9	12,3
	15	12	16	16	12	16	12	6	13,5
									$\overline{}$
	0	0	-	0	0	0	0	٥	0,1
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Itching	9	0	6	7	∞	4	9	9	5,8
		2	. 12	8	11	7	6	6	6'8
ļ	15	9	13	6	16	12	6	12	11,5
	_	7	12	12	4	-	6		
2	4				4	. ,	01	8	11,6
Intensit	9	18	18	21					14,5
	19	18	81	21	14	18	12	15	16,8
	19	18	18	21	14	18	12	15	6,91

### Dynamics of the main symptoms in the case of patients with a severe form of psoriasis

Intensity Itching Erythema Desquamation Desquamation

### Cessation of symptoms

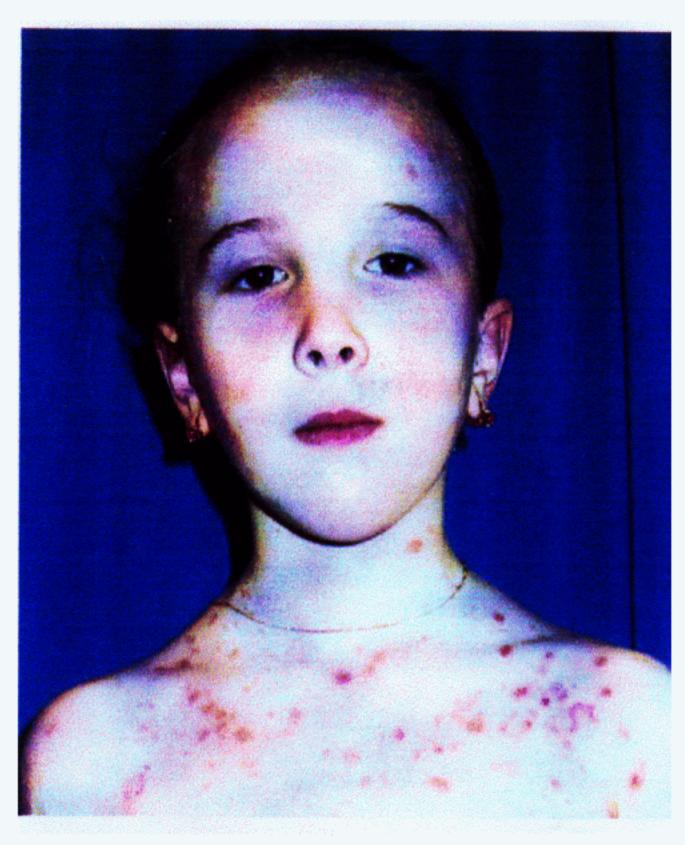
		vist	RTA	Μw	l .
21	m	6	8	9	4
14	1	5	1	4	2
7		3		4	
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Vizsgálati napok	Intensity	Itching	Enythema	Desquamation	Infiltration
Vizs			bliM	I	

Vi	Vizsgálati napok	0	3	7	14	17
	Intensity					2
	Itching		11	3	\$	<u> </u>
acra 19ver	Erythema					7
	Desquamation			4	4	\$
	Infiltration					7

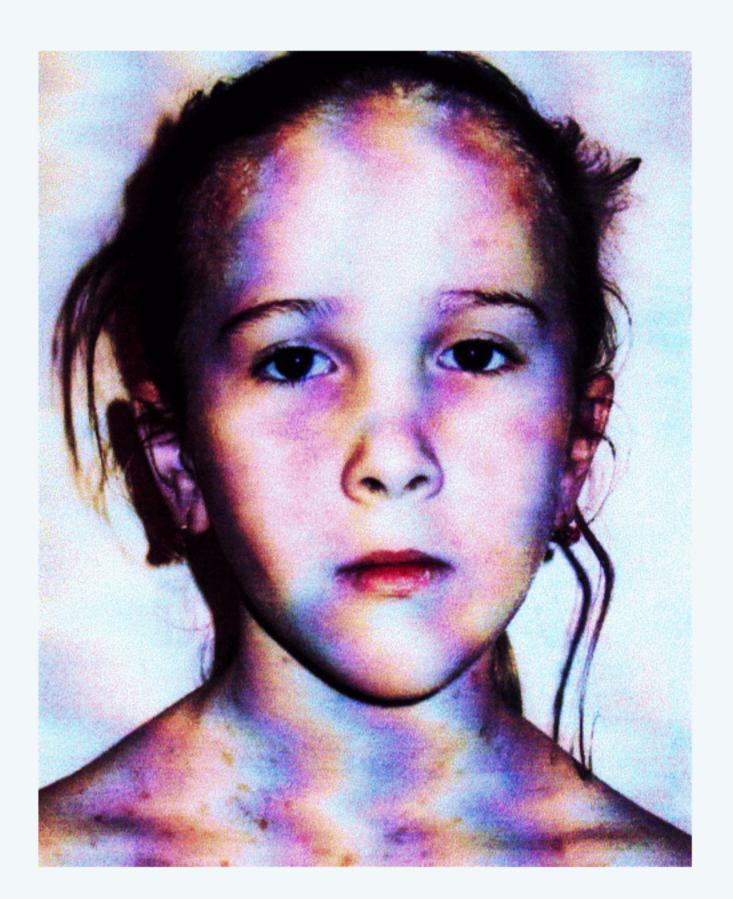
	Vizsgálati napok	0	3	7	14	2.1
	Intensity					
9.	Itching			-	2	<b>-</b>
CVCT	Erythema					   
<u>s</u>	Desquamation				2	4
	Infiltration					7



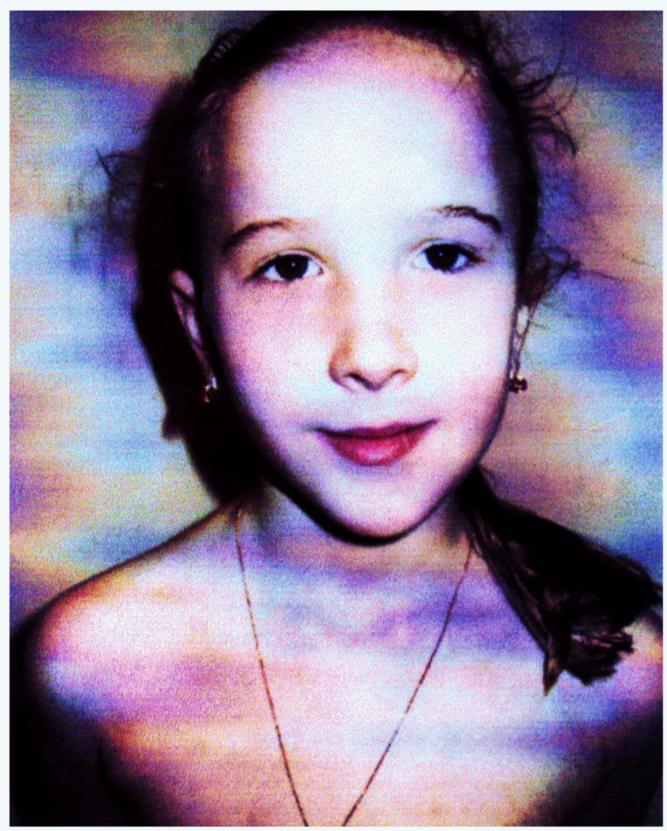
On the 3rd day of the control examination



On the 7<sup>th</sup> day of the control examination



On the 14<sup>th</sup> day of the control examination



On the 21st day of the control examination