Department of Dermatovenereology and Dermatocosmetology

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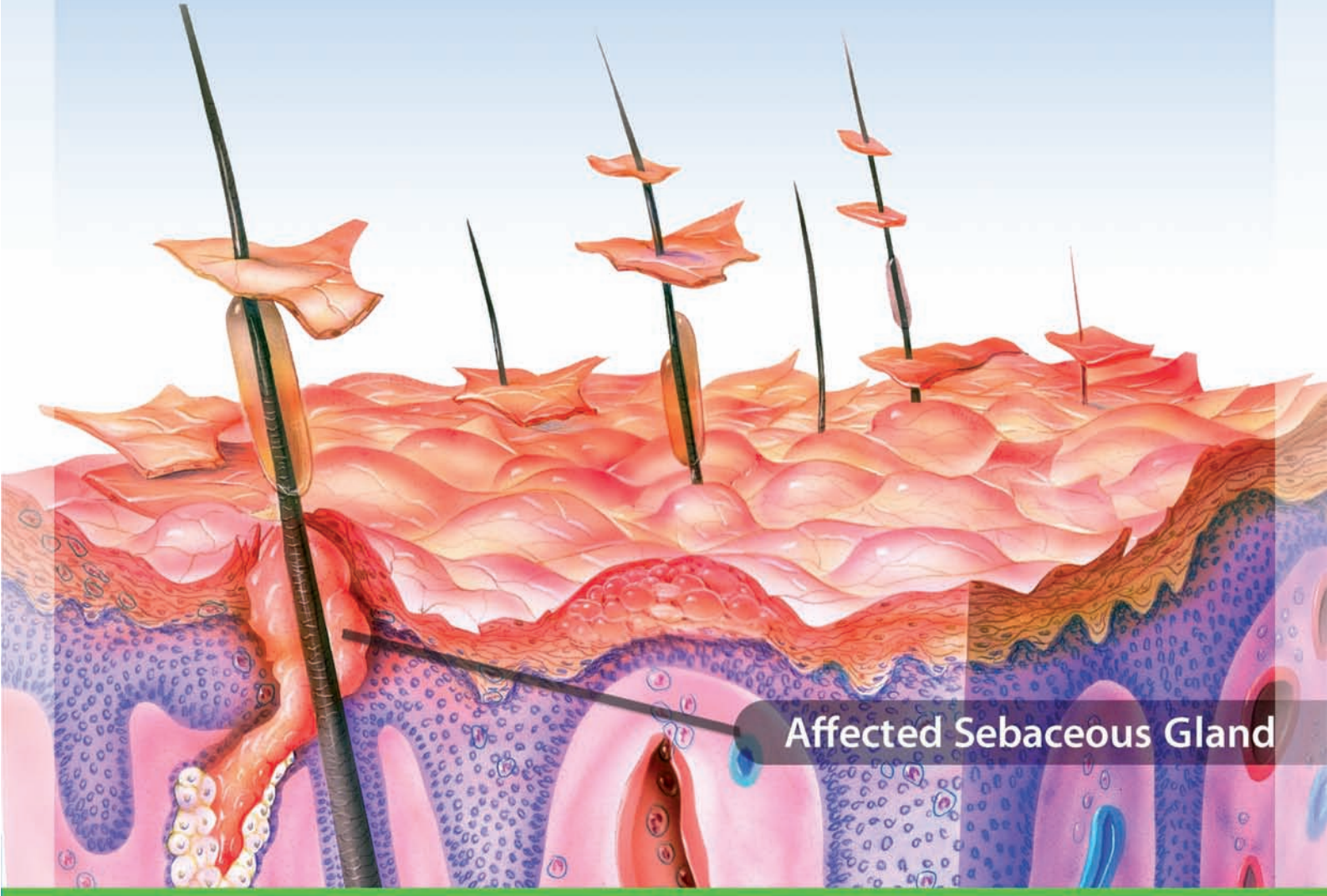

Results of a clinical trial assessment of the effectiveness of BLUE CAP® foam

Results of a clinical trial assessment of the effectiveness of BLUE CAP® Foam

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BACKGROUND

The open prospective multicentre noncomparative clinical research of the efficacy and safety of a 2-week application of the new medication.

The efficacy and safety study of 2 weeks of application of the emollient BLUE CAP® Foam (CATALYSIS, Spain) as a part of the standard therapy of atopic dermatitis, seborrheic dermatitis and psoriasis in patients of different age groups.

THE PURPOSE OF THE ASSESSMENT AND THE FOLLOW-UP

Effectiveness and tolerability of BLUE CAP® Foam with regular use as part of standard therapy for atopic dermatitis, seborrheic dermatitis and psoriasis in patients of different age groups.

METHODS AND RESEARCH

The study involved 30 patients diagnosed with atopic dermatitis, psoriasis and seborrheic dermatitis who were treated with piroctone olamine monotherapy. The age and sex characteristics of the total group were as follows: 15 males, 15 females; the age of the subjects ranged from 4 to 73 years.

Patients diagnosed as having **"Atopic Dermatitis" - 12, "Psoriasis" - 11, "Seborrheic Dermatitis" - 7**.

Diagnosis	Atopic Dermatitis	Psoriasis	Seborrhoeic Dermatitis
Number of patients	(12)	(11)	(7)
Men	6 (50%)	6 (54.5%)	3 (43%)
Women	6 (50%)	5 (45.5%)	4 (57%)
Average age	4 - 38 years Average - 15,3	17 - 73 years Average - 44,3	31 - 62 years Average - 42,3

All subjects used BLUE CAP® Foam twice a day (morning and evening) on the affected areas, the surrounding skin and skin with signs of dryness. **Duration of use: 14 days**

RESULTS OF A STUDY OF 3 GROUPS OF PATIENTS

Atopic Dermatitis

The following tests were performed on 12 patients with atopic dermatitis:

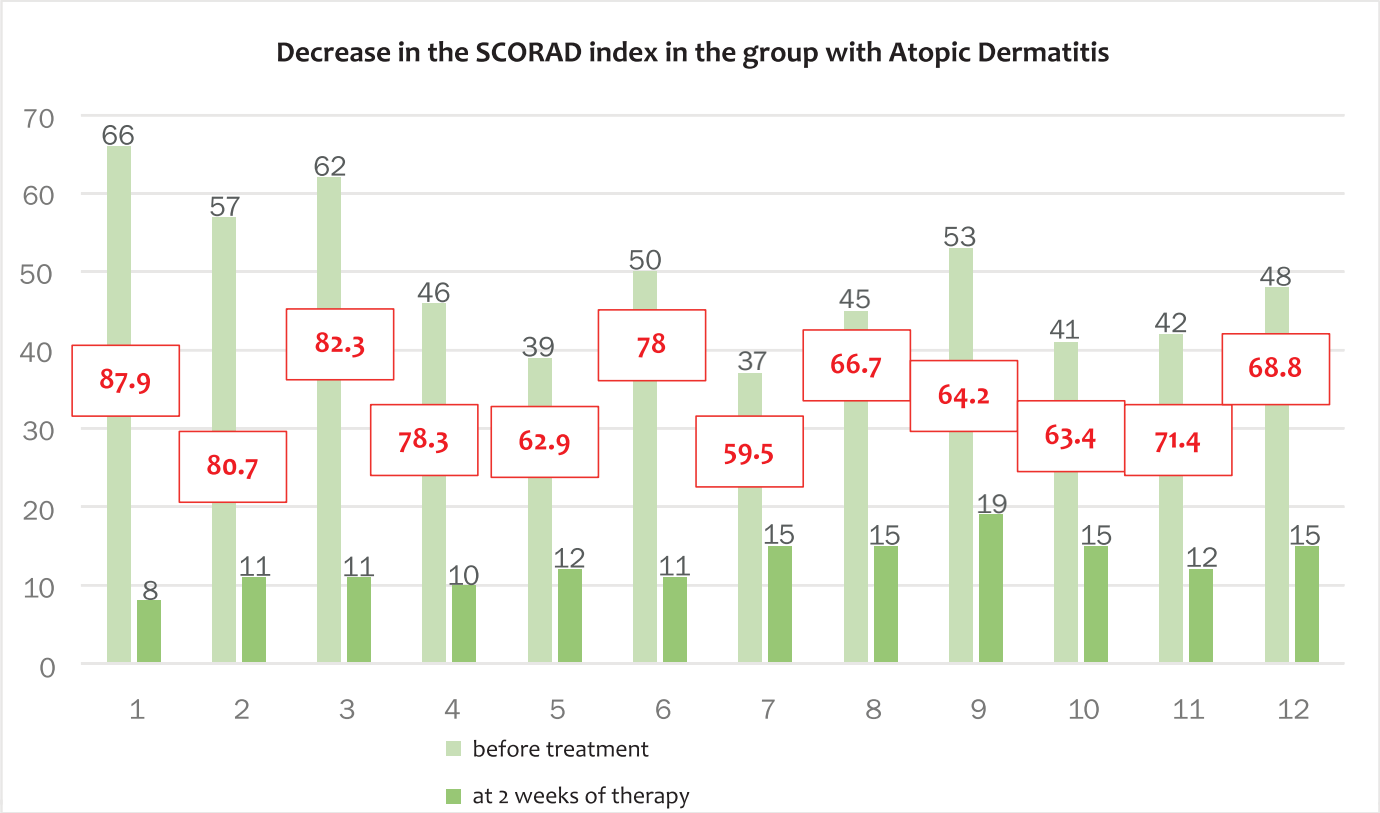
- Assessment of the severity of atopic dermatitis by the Scoring of Atopic Dermatitis (SCORAD) index;
- Assessment of the intensity of itching on a visual analogue scale (VAS);
- Assessment of quality of life in patients with atopic dermatitis using the Dermatology Quality of Life Index (DLQI) questionnaire DLQI (Dermatology Life Quality Index);
- Assessment of the organoleptic properties of the cosmetic (odour, texture / consistency) based on a five-point scale completed by patients;
- Assessment of the frequency and severity of adverse events.

RESULTS TABLE

	Patient code	Gender	Age	SCORAD		VAS		DLQI		Organoleptics	Adverse Effects
				1	2	1	2	1	2		
1	ШО-1	M	17	66	8	9	1	21	3	5	Burning
2	БМ-2	W	8	57	11	9	0	-	-	5	-
3	КА-3	W	12	62	11	8	1	-	-	5	-
4	БЮ-4	W	38	46	10	6	0	20	4	4	Burning
5	АЕ-5	M	4	39	12	5	0	-	-	5	-
6	МИ-19	M	7	50	11	7	2	-	-	5	-
7	ЮА-20	W	5	37	15	6	1	-	-	5	-
8	НА-24	M	01	45	15	8	3	-	-	5	-
9	ММ-25	W	34	53	19	7	3	14	6	4	
10	СБ-28	M	19	41	15	7	3	7	2	5	Burning
11	ГГ-29	W	24	42	12	6	3	26	8	5	-
12	АТ-30	M	6	48	15	7	3	-	-	5	-

Patients in the study group had a SCORAD score at the start of treatment of 48.8, of whom 5 patients (42%) had a score above 50, corresponding to a severe course of atopic dermatitis; 7 patients (58%) had a score between 25 and 50, corresponding to an average severity of the disease.
After 2 weeks of treatment, SCORAD averaged -12.8, a 73.8% reduction in the overall index in the group.

The individual values for each patient are shown in **figure 1**



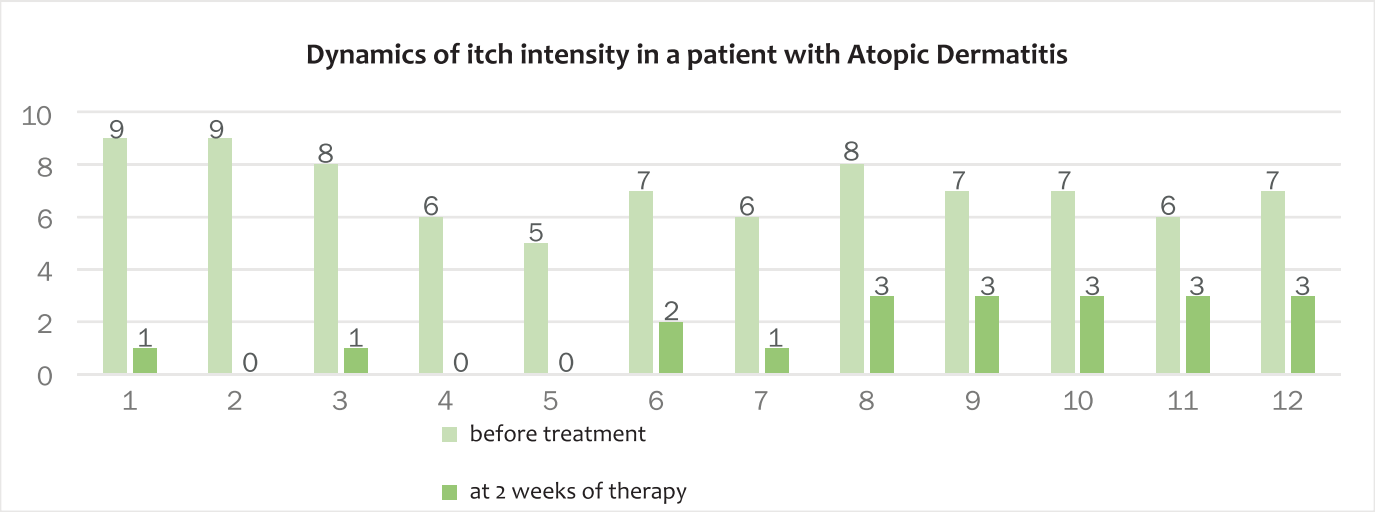
* Note the red box shows the percentage decrease in each case

Itching intensity in the visual analogue study group.
The scale (VAS) at the beginning of treatment was evaluated by the patients as follows:

- 1 patient - 8.3% - mild
- 9 patients - 75% - moderate
- 2 patients - 16.7% - severe

After 2 weeks of therapy: in 5 patients (41.7%) weak registered intensity (lower threshold) - 3 points.
The average indicator in the group: before treatment - 7.1, after 2 weeks of therapy - 1.7.

The individual values for each patient are shown in **figure 2**



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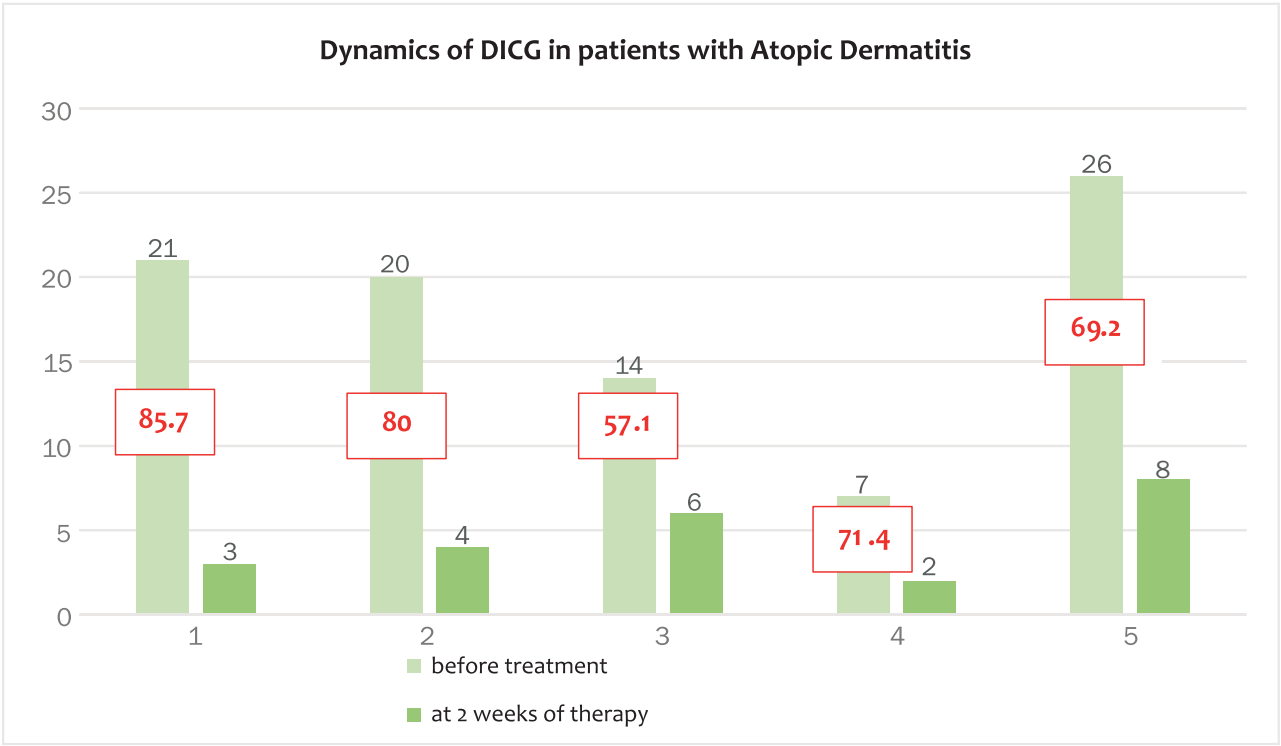
As the DICG index is intended for patients over 16 years of age, the results for this part of the study are presented for 5 patients only:

At the start of therapy, the group average was - 17.6 (2 patients - at the start of therapy, the mean score was 17.6 (2 patients severely affected, 2 severely affected, 1 moderately affected); after 2 weeks of treatment, the mean score was 4.6 (2 patients moderately affected, 3 mildly affected). The overall reduction in the group was 73.9%.

The individual values for each patient are shown in **figure 3**



* Note the red box shows the percentage decrease in each case

Average assessment of the organoleptic properties of a cosmetic product (smell, texture/consistency) according to the results of filling in the five-point scale by patients - 4.8 points out of 5.

Adverse events using the medicine were reported in 3 patients (25%) in the form of a slight burning sensation in the first minutes after application.

Psoriasis

In the study, 11 patients with psoriasis underwent the following:

Investigations:

- Assessment of the prevalence and severity of psoriasis using the Psoriasis Area and Severity Index (PASI) and Body Surface Area (BSA);
- Assessment of the quality of life of psoriasis patients using the Dermatology Life Quality Index (DLQI) questionnaire;
- Evaluation of the organoleptic properties of the cosmetic product (odour, texture/conformity) by completing the patients on a five-point scale;
- Assessment of the frequency and severity of adverse events.

RESULTS TABLE

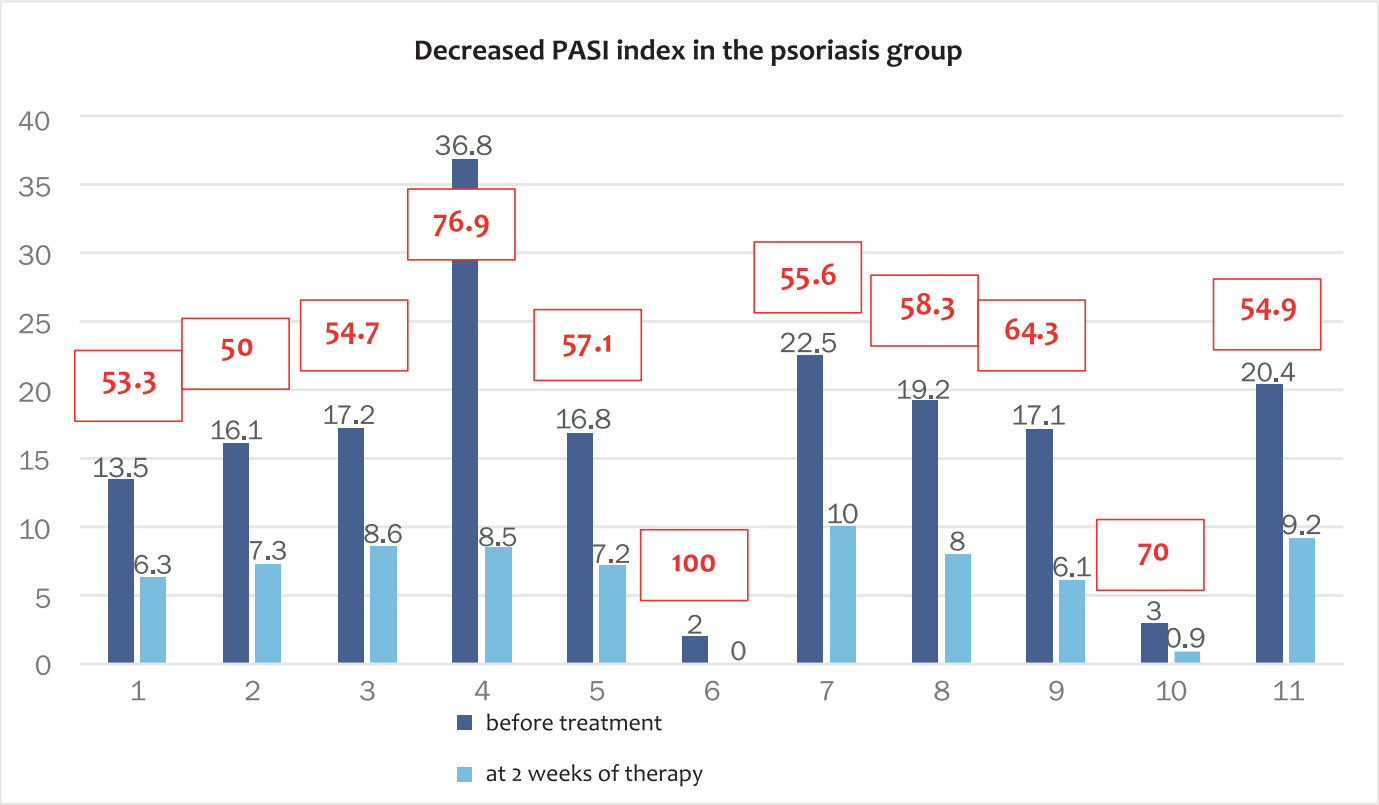
	Patient code	Gender	Age	PASI		BSA		DLQI		Organoleptics	Adverse Effects
				1	2	1	2	1	2		
1	КЭ-7	M	52	13,5	6,3	ум	ум	10	6	5	-
2	РМ-8	M	17	16,1	7,3	ум	л	17	6	3	Burning
3	ТР-9	W	56	17,2	8,6	ум	ум	13	5	4	-
4	АА-6	W	31	36,8	8,5	т	ум	27	11	5	-
5	ТК-10	M	37	16,8	7,2	ум	л	12	9	5	-
6	КА-11	W	20	2	0	л	л	7	0	5	-
7	АК-12	M	39	22,5	10,0	т	ум	24	12	5	-
8	ГМ-21	M	73	19,2	8,0	ум	л	10	4	5	-
9	СТ-22	W	60	17,1	6,1	ум	л	12	5	4	Burning
10	ОГ-26	W	44	3	0,9	ум	л	9	3	5	-
11	ШМ-27	M	58	20,4	9,2	ум	ум	16	5	5	-

ум - arms and legs л - head and face т - body

In patients in the study group, the PASI indicator at the beginning of the average was 16.8, of which 2 patients (18.2%) - with an indicator of less than 10, corresponding to a mild degree of psoriasis; 6 patients (54.5%) with an indicator of 10-20, corresponding to moderate severity of the disease, 3 patients (27.3%) with an indicator of more than 20 - severe severity of psoriasis.

After 2 weeks from the start of therapy, the average PASI score in the group rose to 6.6, i.e. the overall decrease of the index in the group - by 60.7%. rose to 6.6, i.e. the overall decrease of the index in the group - by 60.7%.

The individual values for each patient are shown in **figure 4**



* Note the red box shows the percentage decrease in each case

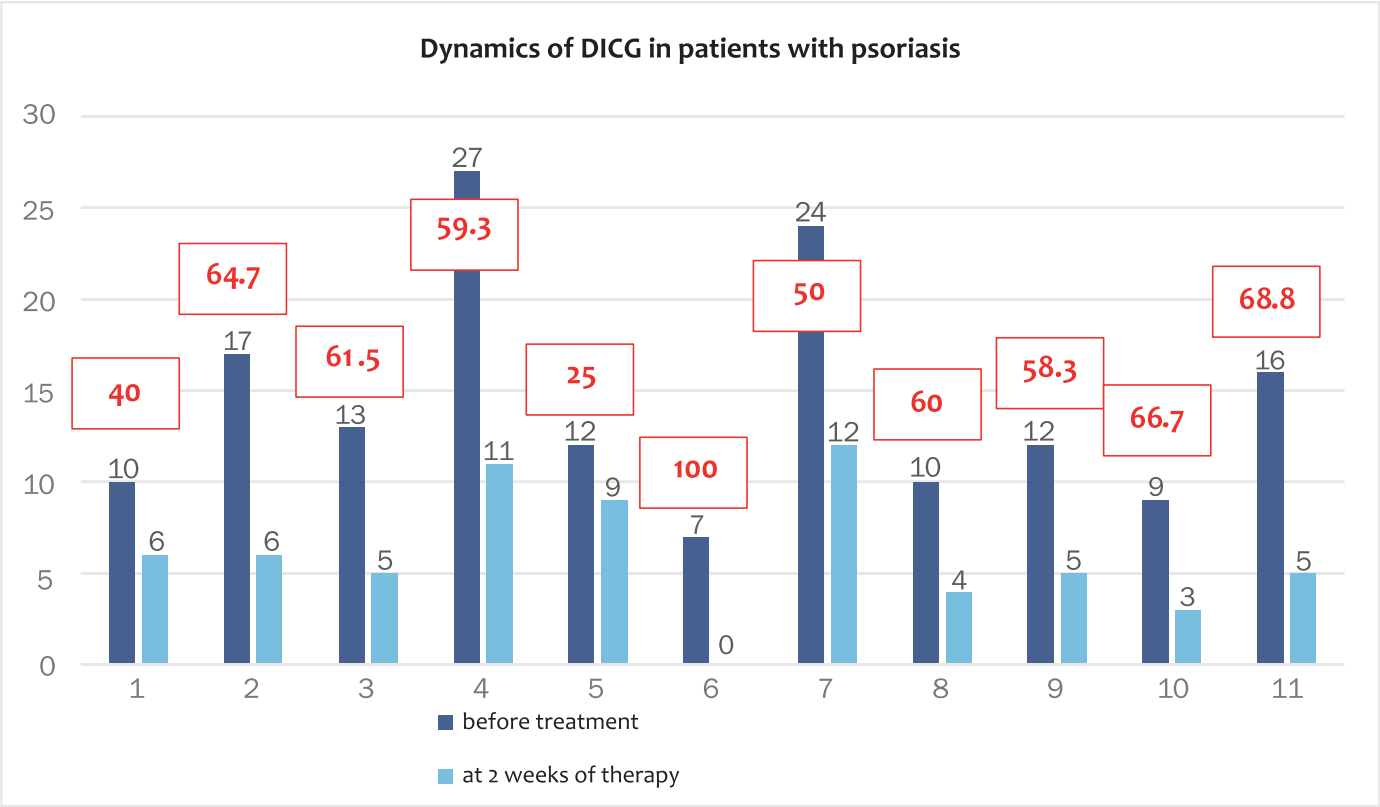
There is a system of assessing the efficacy of the therapy in psoriasis, where a 25% decrease in PASI from baseline is considered to be ineffective, 25 to 49% - a slight improvement, 50 to 74% - improvement, more than 75% - a significant improvement.
In our study, 9 patients (82%) could be regarded as "improved" by treatment, in 2 cases as "significantly improved".

The prevalence and severity of psoriasis according to the Body Surface Area Index (BSA) at the start of treatment was assessed as follows:

- 1 patient - 9.1 % - mild degree (lesion area less than 5 %)
- 8 patients - 72.7% - moderate (lesion area 5-10%)
- 2 patients - 18.2% - severe (lesion area greater than 10%).

After 2 weeks of therapy: 6 patients (54.5%) had a mild degree of involvement, 45.5% - moderate. No change in the extent and severity of the process was registered in 3 cases - 27.3%.
At the start of treatment, the mean **DICG index** score for the group was 14.3 (2 patients severely affected, 5 patients severely affected, 4 patients moderately affected); after 2 weeks of treatment, the mean score was 6 (1 patient - no effect, 5 patients slightly affected, 2 patients moderately affected). **Total reduction in the group - 58%.**

The individual values for each patient are shown in **figure 5**



* Note the red box shows the percentage decrease in each case

The **average rating of the organoleptic properties** of the product (smell, texture/constitution) on a five-point scale by patients was 4.6 out of 5.

Unwanted phenomena during use of the drug were recorded in 2 patients (18.2%) in the form of a slight recurring burning sensation in the first minutes after application.

Seborrheic Dermatitis

Seven patients with seborrheic dermatitis were investigated as follows:

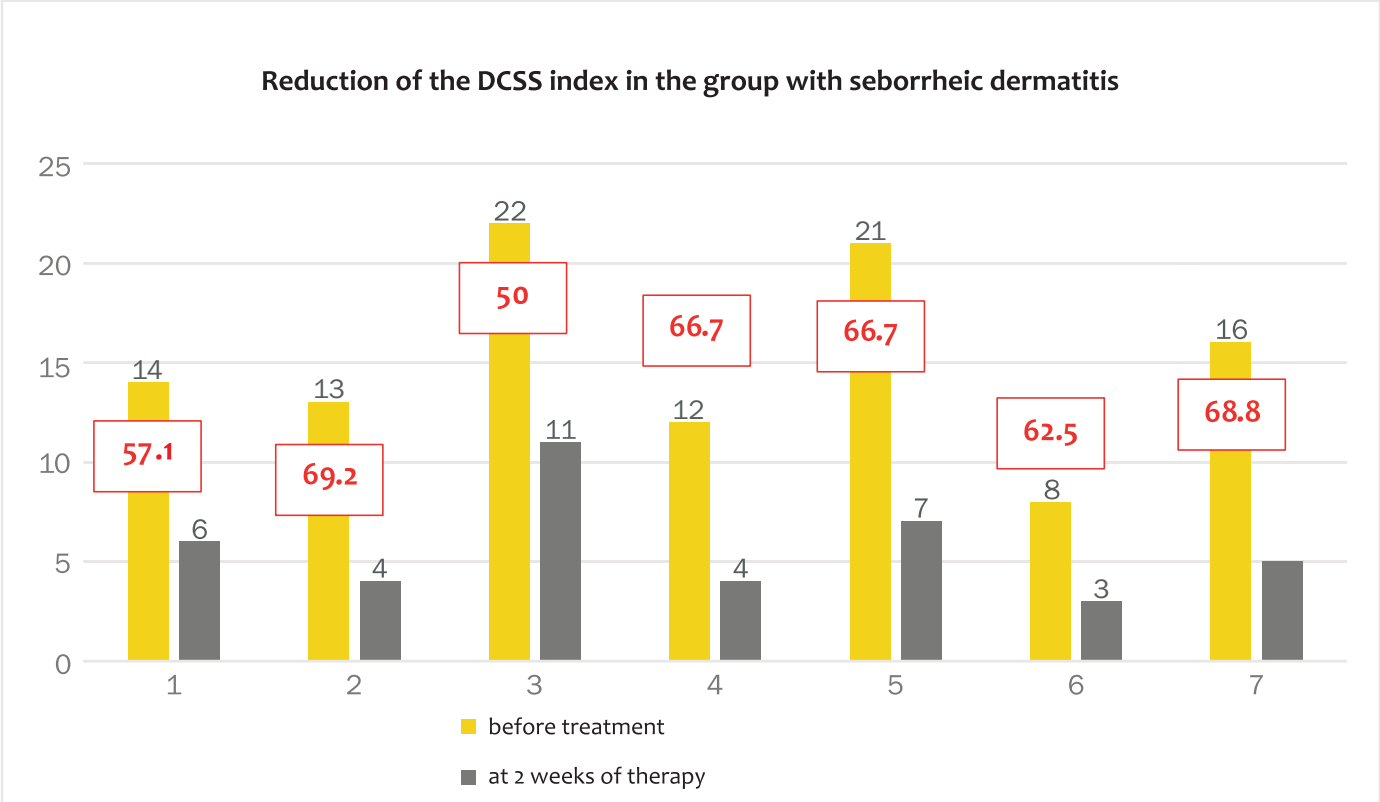
- Assessment of the severity of the course of seborrheic dermatitis using the DCSS (Dermatology Clinical Sign Score) dermatology symptom index;
- Assessment of the quality of life of patients with seborrhoeic dermatitis using a questionnaire. Dermatology Life Quality Index (DLQI);
- Evaluation of organoleptic properties of cosmetic products (odour, texture/consistency) based on a five-point scale completed by patients;
- Assessment of the frequency and severity of adverse events.

RESULTS TABLE

	Patient code	Gender	Age	DCSS		DLQI		Organoleptics	Adverse Effects
				1	2	1	2		
1	КТ-13	W	62	14	6	12	5	5	Burning, reddening in the first hours
2	ММ-14	W	33	13	4	19	5	5	-
3	НИ-15	W	56	22	11	9	3	5	-
4	КВ-16	M	37	12	4	8	1	5	-
5	ПИ-17	M	43	21	7	13	4	3	-
6	МА-18	W	31	8	3	22	6	4	-
7	ТВ-23	M	36	16	5	13	5	4	Burning, reddening in the first hours

The dermatological severity of seborrhoeic dermatitis using the DCSS symptom scale index averaged 15.1 at the start of treatment and 5.7 after 2 weeks of treatment, i.e. a 62.3% reduction in the overall index in the group.

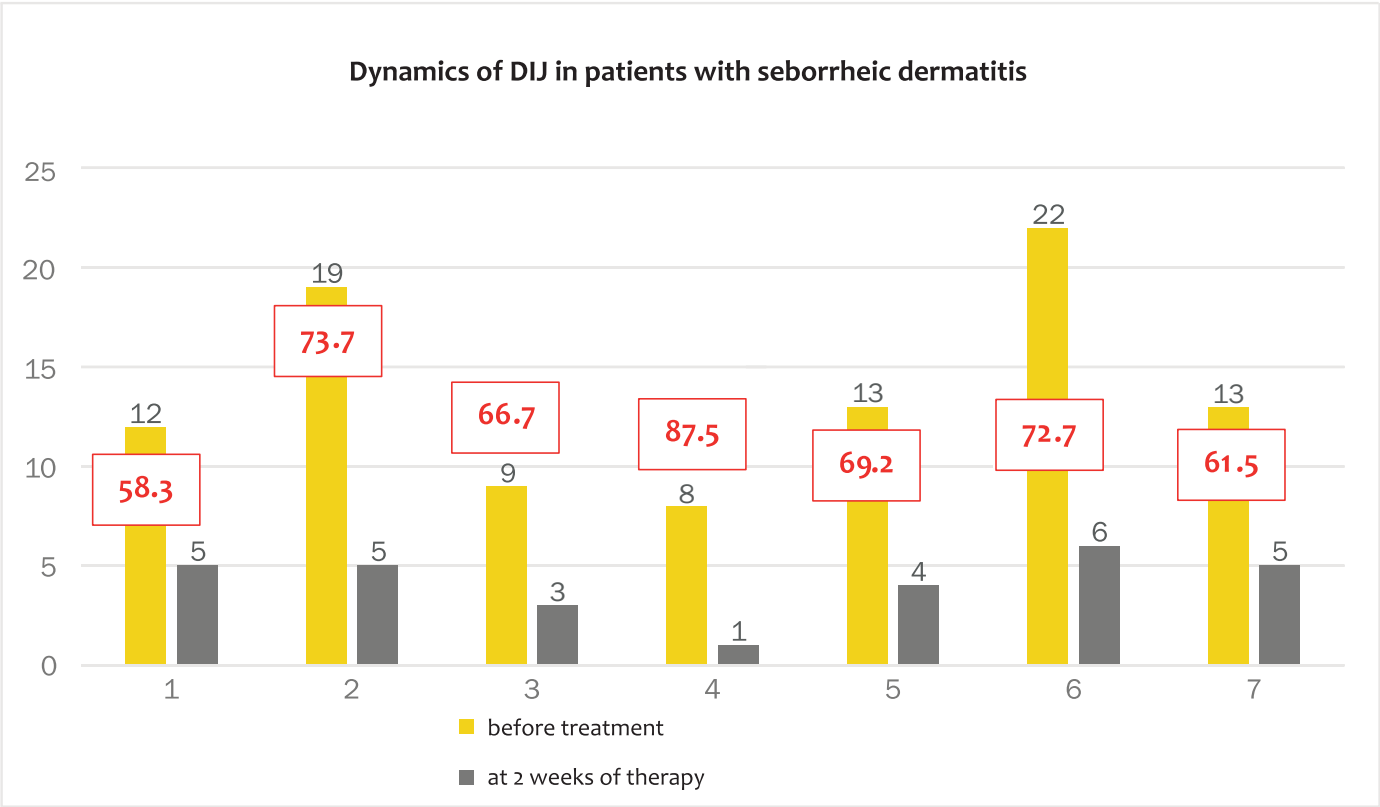
The individual values for each patient are shown in **figure 6**



* Note the red box shows the percentage decrease in each case

At the start of therapy, the **average DCSS index** for the group was - 13.7 (1 patient - extremely high impact on quality of life, 4 patients - very high impact, 2 patients - moderate impact); after 2 weeks of therapy, the average index was 4.1 (1 patient - no impact, 5 - minor impact, 1 patient - moderate impact).
The overall reduction in the group was 70.1%.

The individual values for each patient are shown in **figure 7**



* Note the red box shows the percentage decrease in each case

Average evaluation of the organoleptic properties of a cosmetic product (smell, texture / consistency) according to the results of filling the five-point scale by patients - 4.4 points out of 5.

Adverse events using the medicine

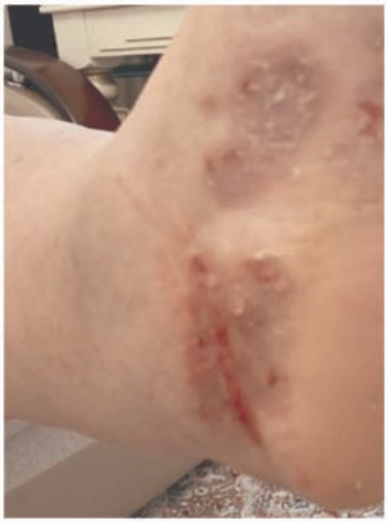
Were reported in 2 patients (28.6%) in the form of a slight burning sensation in the first minutes after application, which is most likely due to the delicate area of application (face, scalp).

CONCLUSIONS OF THE STUDY

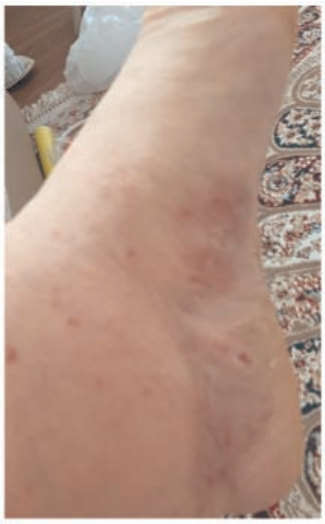
The use of BLUE CAP® Foam as an external agent in patients with atopic dermatitis, psoriasis and seborrhoeic dermatitis has proven effective, led to a clinical improvement of diseases with a two-week course of therapy and can be recommended as monotherapy for these pathologies.

PHOTO DOCUMENTATION

Patient: Woman, 56 years old.
Diagnosis: Psoriasis.

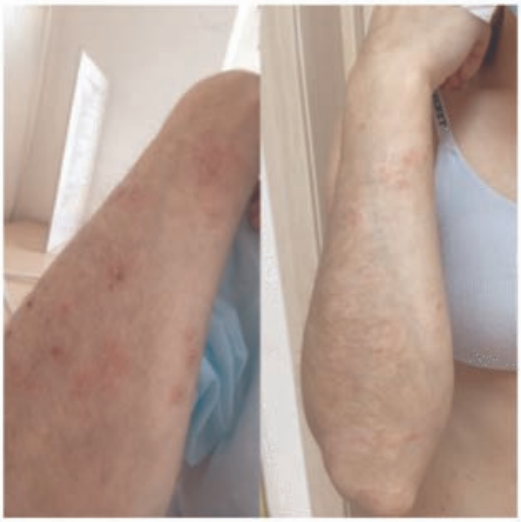


Before treatment

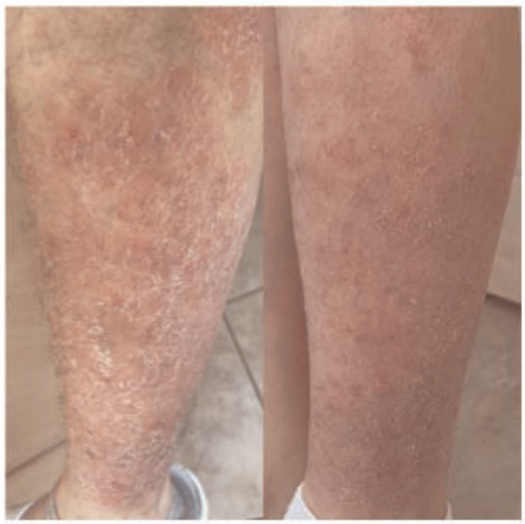


At 14 days of therapy

Patient: Woman, 31 years old.
Diagnosis: Psoriasis.

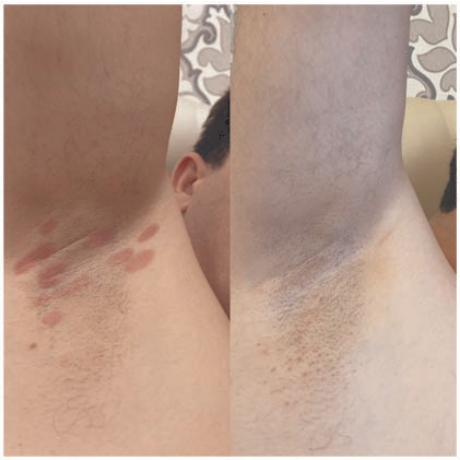


Before treatment At 7 days of therapy



Before treatment At 7 days of therapy

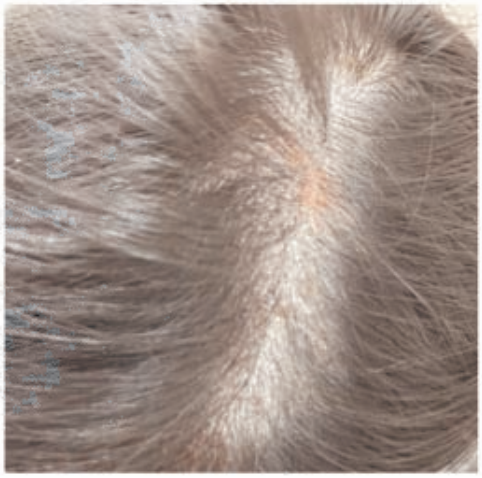
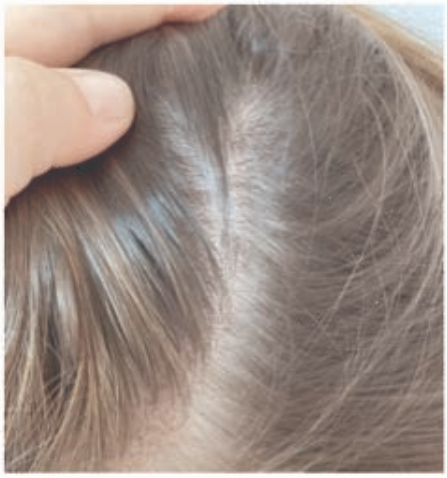
Patient: Man, 37 years old.
Diagnosis: Psoriasis.



Before treatment At 14 days of therapy

PHOTO DOCUMENTATION

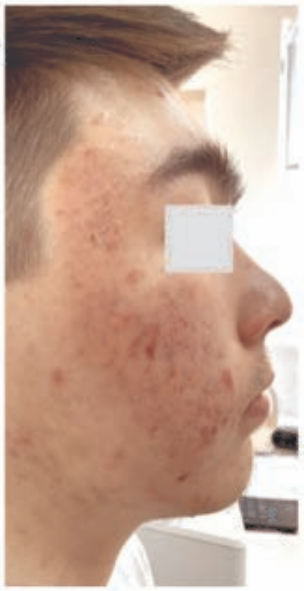
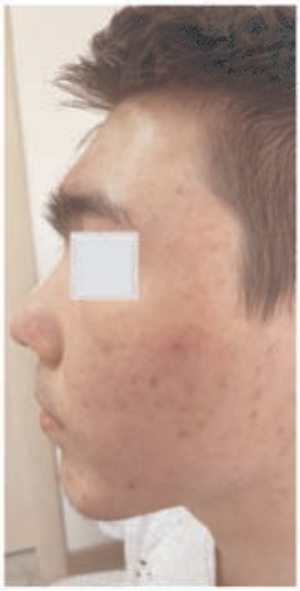
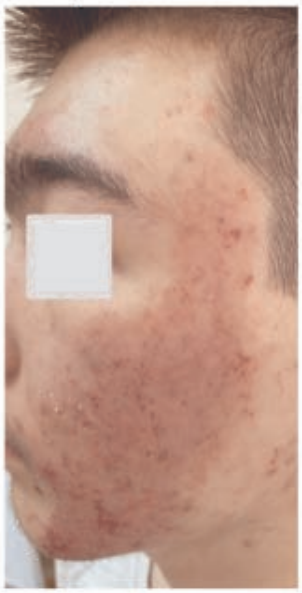
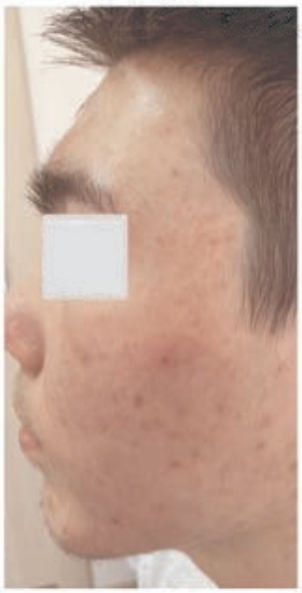
Patient: Girl, 20 years old.
Diagnosis: Psoriasis head.

Before treatment

At 14 days of therapy

Patient: Boy, 17 years old.
Diagnosis: Atopic dermatitis.

Before treatment

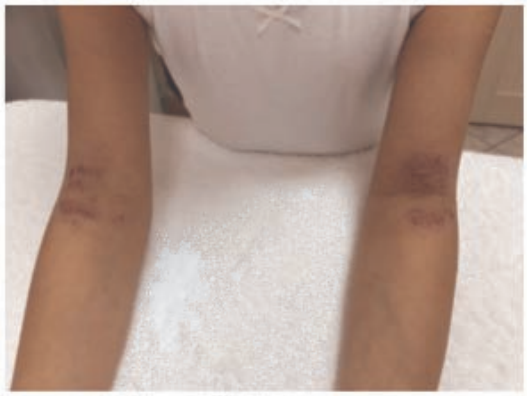
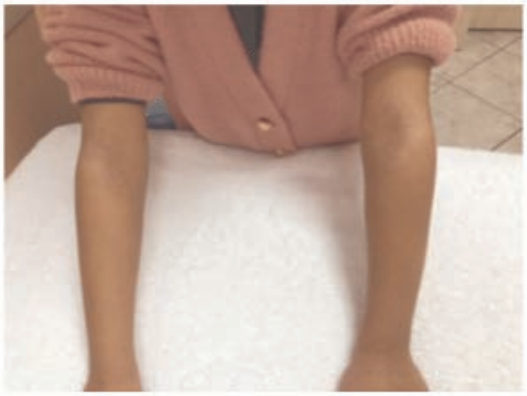
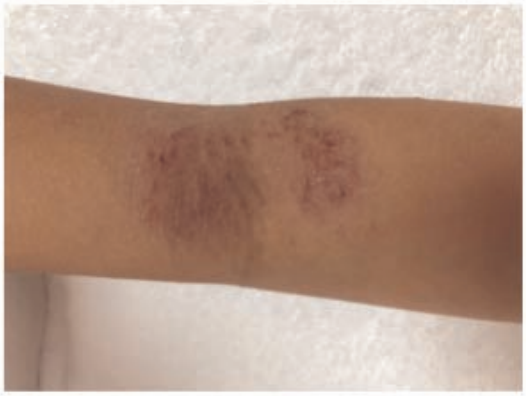
At 14 days of therapy

Before treatment

At 14 days of therapy

PHOTO DOCUMENTATION

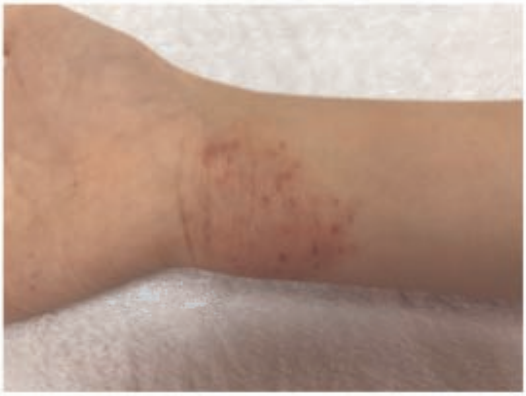
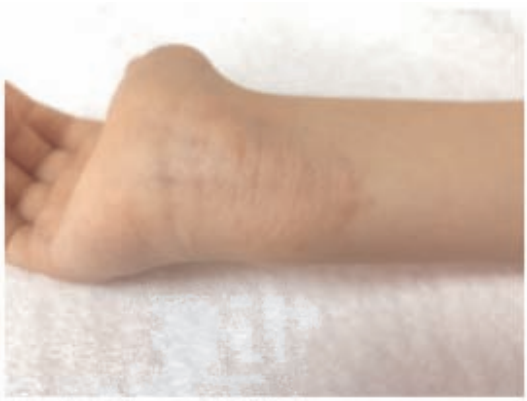
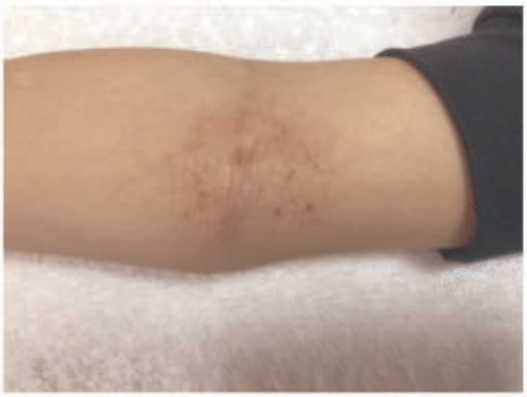
Patient: Girl, 8 years old.
Diagnosis: Atopic dermatitis.


Before treatment

At 14 days of therapy

Patient: Girl, 12 years old.
Diagnosis: Atopic dermatitis.

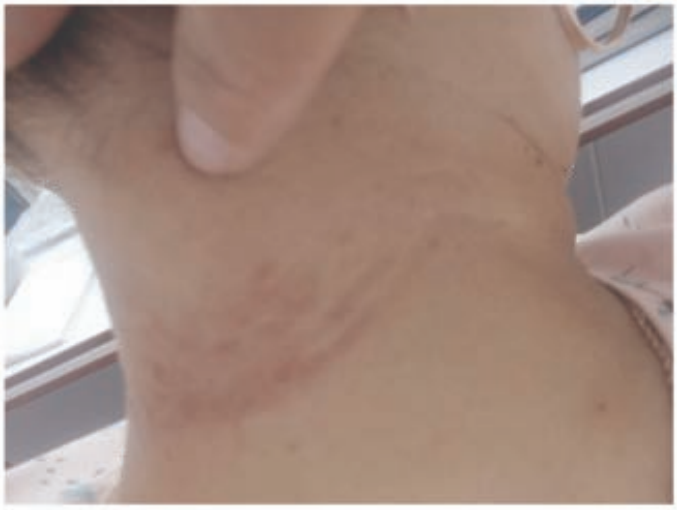





Before treatment

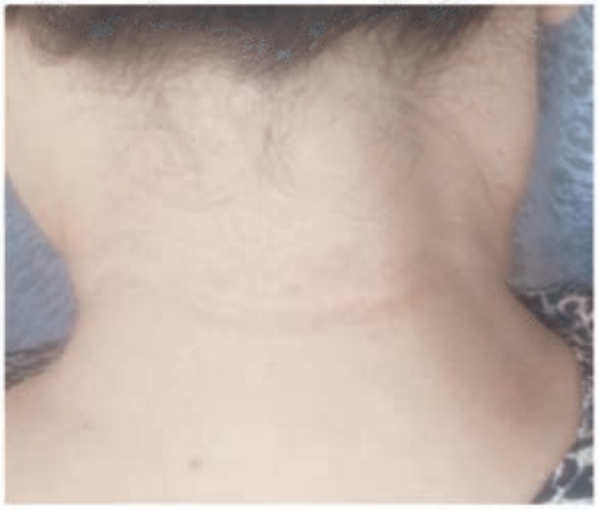
At 14 days of therapy

PHOTO DOCUMENTATION

Patient: Girl, 38 years old.
Diagnosis: Atopic dermatitis.

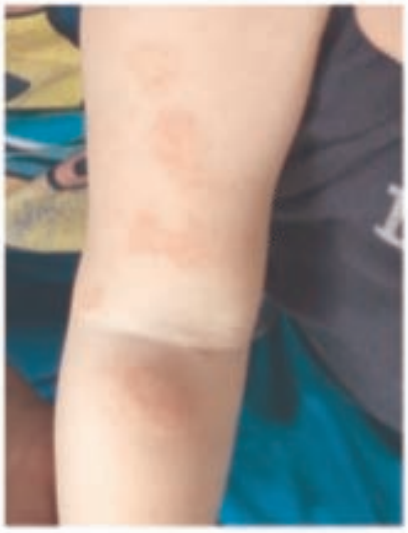


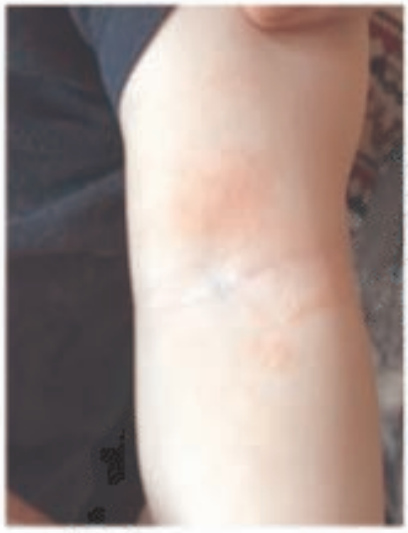
Before treatment

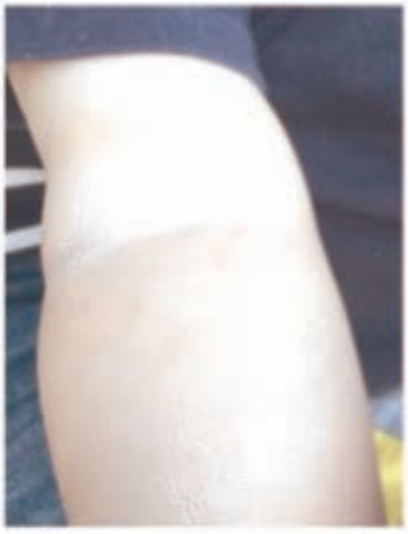


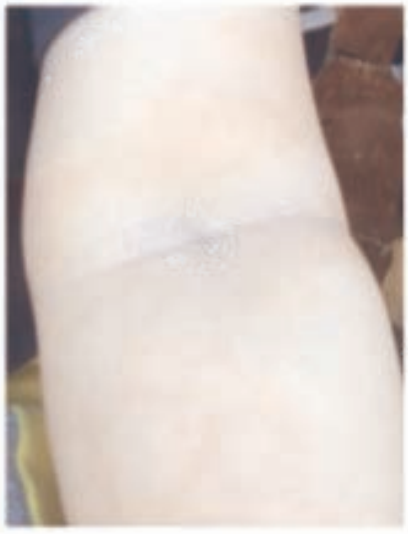
At 14 days of therapy

Patient: Child, 4 years old.
Diagnosis: Atopic dermatitis.







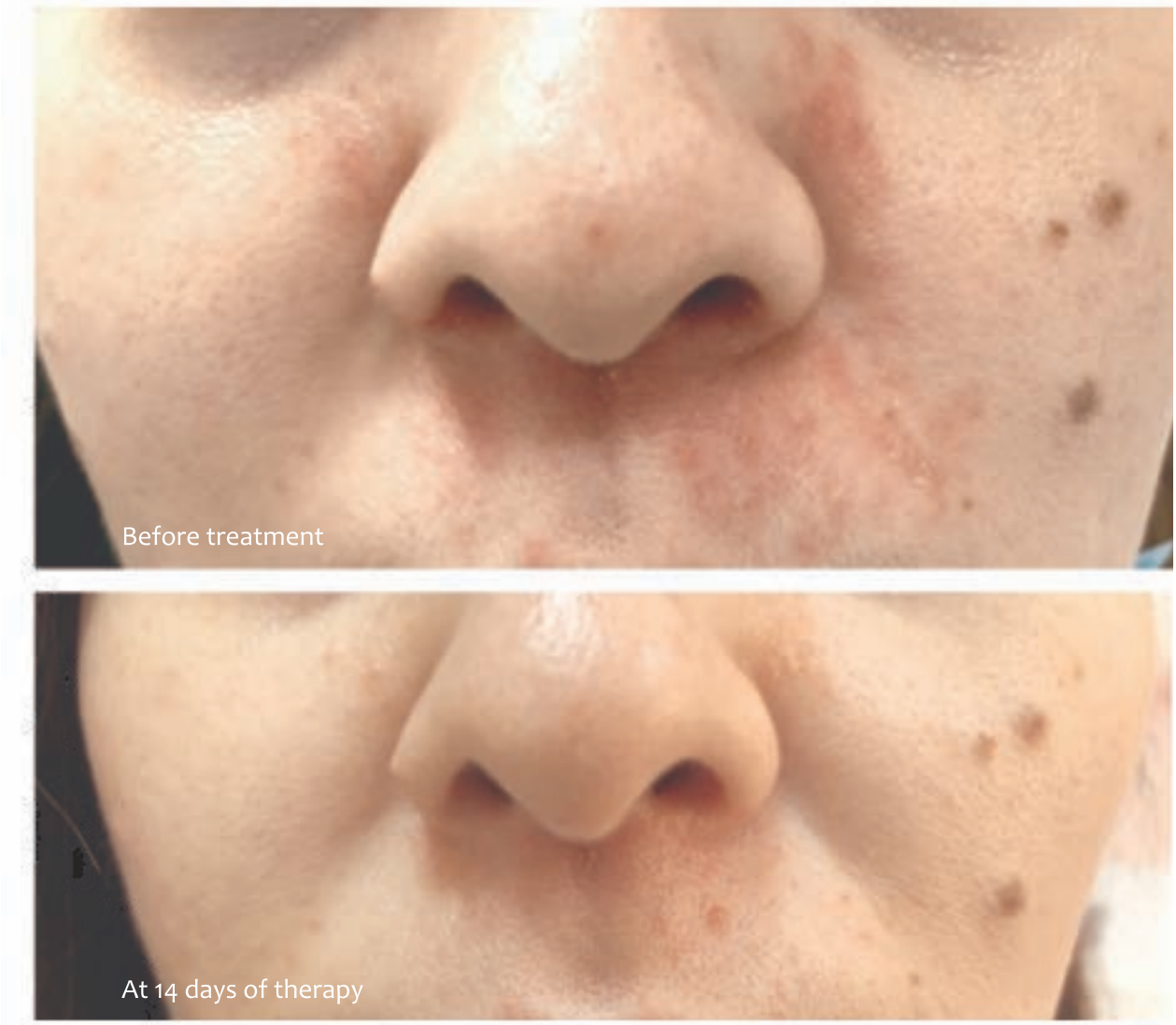


Before treatment

At 14 days of therapy

PHOTO DOCUMENTATION

Patient: Woman, 33 years old.
Diagnosis: Atopic dermatitis.



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