

# A NEW TOPICAL CORTICOSTEROID: CLOCORTOLONE CREAM

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Clocortolone pivalate (Purantix<sup>(R)</sup> Sandoz) is a new dihalogenated corticosteroid for topical use, 9 $\alpha$ -Chloro-6 $\alpha$ -fluoro-11 $\beta$ , 21-dihydroxy-16 $\alpha$  methyl-pregna-1, 4-diene-3,20-dione 21 pivalate. Its anti-inflammatory action and good tolerance have been demonstrated in animal experiments. In the granuloma-pouch test, its activity when administered by the oral or subcutaneous route has been shown to be approximately thirty times that of hydrocortisone acetate. An open clinical trial was undertaken to evaluate its efficacy and tolerance, when used at a concentration of 0.1% in an oil-in-water base, in dermatoses normally responsive to topical corticosteroids.

## Method

One hundred and one patients with the following diagnoses were treated:

Psoriasis vulgaris (20)  
Contact dermatitis (23)  
Lichen chronicus simplex (9)

Atopic dermatitis (6)  
Pompholyx (3)  
Seborrhoeic eczema (2)  
Nummular eczema (2)  
Pruritus in association with varicose veins (1)  
Infective dermatitis (1)  
Acne vulgaris (9)  
Keloid scars (8)  
Pruritus ani (5)  
Herpes simplex (1)  
Pityriasis rubra pilaris (1)  
Dermatitis papillaris capilliti (2)

Fifty-three of these patients were male and forty-eight female. Only five were inpatients. Ages ranged from 3 months to 75 years but 87 were over 14. The cream was applied two to four times daily, in conformity with normal practice, and was continued until its maximum effect was deemed to have been achieved. This averaged 26.7 days (range 8-51 days). Two patients only were treated for part of the time with occlusive dressings which were changed 3 and 7 times per week respec-

Diagnosis	Acute-weeping	Acute	Sub-acute	Chronic	Total
Psoriasis vulgaris	—	1	9	10	20
Eczema	1	8	32	6	47
Others	—	4	19	11	34

TABLE I

tively. Both were cases of psoriasis. During the trial period, no other topical medicaments were applied except for potassium permanganate lotions or baths. No antibiotics or systemic steroids were administered.

#### Assessment

For the purposes of evaluation, cases were grouped into three categories, viz psoriasis vulgaris, eczema (including contact dermatitis, lichen chronicus simplex, pompholyx, atopic dermatitis, seborrhoeic eczema, nummular eczema, pruritus associated with varicose veins, and infective dermatitis) and 'other indications' (acne vulgaris, keloid scars, pruritus ani,

discoid lupus erythematosus, herpes simplex, pityriasis rubra pilaris, lichen planus, and dermatitis papillaris capilliti). Table I summarises the diagnostic distribution of the patients and the state of the lesions they exhibited.

Assessment of efficacy was based on:

- recording of the following target symptoms on a four-point severity scale before and after treatment: erythema, weeping, scaling, pruritus, lichenification;
- overall assessments at the end of the trial by the investigator and the patients separately of efficacy on a five-point scale.

Local and general side effects were also recorded.

Effectiveness	Eczema		Psoriasis		Other indications	
	Physician	Patient	Physician	Patient	Physician	Patient
very effective	25	35	2	9	9	16
effective	21	10	7	5	8	4
moderately effective	1	2	9	4	9	8
slightly effective	—	—	1	1	3	—
not effective	—	—	1	1	5	6
TOTAL	47		20		34	

TABLE II Overall Assessment

Diagnosis	Erythema	Weeping	Scaling	Pruritus	Lichenifications
Eczema	70.7% (41)	100% (10)	92.3% (26)	92.5% (40)	87.7% (7)
Psoriasis	20.0% (20)		44.4% (18)		
Other indications	35.7% (28)		50.0% (6)	100% (11)	50.0% (2)

**TABLE III Percentage of Patients with Complete Regression of Symptoms**  
Numbers in brackets refer to number of cases showing each symptom at start of trial.

### Results

Clocortolone was judged by the investigator as being effective or very effective in 71.3% of cases. It was considered moderately effective in another 18.7% and ineffective or only slightly effective in the remaining 9.9% (Table II).

Target symptoms in eczema resolved completely in between 70.7% (for erythema) and 100% (for weeping) of cases. Pruritus was relieved in 92.5% of cases of eczema and in 100% of the 'other indications'.

Average scores for target symptoms before and after treatment were calculated and the differences between pretreatment and post-treatment average scores were examined for significance by the t-test. The differences were highly significant in eczema for erythema, scaling and pruritus, and in psoriasis for both erythema and scaling (Table IV).

### Discussion

In the *eczemas*, treatment was effective or very effective in no less than 46 of the 47 cases studied. In the remaining patient, clocortolone was judged moderately effective. In *psoriasis*, treatment was considered to be very effective in only 2 cases out of the 20 as judged by the investigator. Nevertheless, the improvement of both target symptoms was statistically highly significant and it is noteworthy that in the opinion of the patients

the treatment was very effective in 9 cases, effective in 5 and moderately effective in 4, only in one case being slightly effective and in 1 ineffective. Not unexpectedly, clocortolone proved disappointing in *acne vulgaris* and in *keloid* scars. In eight cases of *keloid*, treatment was moderately effective in 4, and slightly effective or ineffective in the other 4. In *acne vulgaris*, it was very effective in one case, effective in three cases, moderately effective in one case and slightly effective or ineffective in the remaining four. In the 5 cases of *discoid lupus erythematosus*, treatment was effective in 4 and very effective in 1. The result in the one case of *herpes simplex* was assessed as very effective. Of particular interest was the one case of *pityriasis rubra pilaris* who had been attending the clinic for 13 years and received numerous treatments without any effect but who responded rapidly and dramatically to clocortolone with complete resolution. The most striking experience in the trial of this new product was its effectiveness in pruritic states. In all 5 cases of *pruritus ani* relief was complete, prompt and enduring although most of them were long-standing. Of the 40 cases of eczema which presented with pruritus, 37 (92.5%) attained complete resolution of this symptom. There were no general side effects in any patients. The only local side effect encountered was a mild local irritation in one patient only.

Diagnosis	Symptom	Average Score		Difference	t-Test
		Pre-treatment	Post-treatment		
Eczema	Erythema	2.0	0.3	-1.7	highly significant
	Weeping	1.9	0.0	-1.9	significant
	Scaling	1.6	0.1	-1.5	highly significant
	Pruritus	2.2	0.1	-2.1	highly significant
	Lichenification	1.7	0.1	-1.6	not significant
Psoriasis	Erythema	2.0	0.9	-1.1	highly significant
	Scaling	2.2	0.7	-1.5	
Other Indications	Erythema	1.9	0.8	-1.1	
	Scaling	1.7	0.5	-1.2	not tested due to small numbers of each indication
	Pruritus	2.3	0.0	-2.3	
	Lichenification	2.0	1.0	-1.0	

TABLE IV Significance of differences between pre- and post-treatment average scores.

#### Summary

In a study of 101 cases, clocortolone was shown to be highly effective in the treatment of various forms of eczema and dermatitis. It was also shown to be effective or moderately effective in most cases of psoriasis. There were mixed results in a heterogeneous group of 34 patients with other indications. Outstanding benefit was obtained in the relief of pruritus in all conditions in which this symptom occurred, and particularly in pruritus ani.

Local and systematic tolerance was excellent.

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