

## CLINICAL EVALUATION OF FLUMETHASONE PIVALATE (LOCACORTEN)\* WITH NEOMYCIN AS A TOPICAL CORTICOSTEROID

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Flumethasone pivalate is a new clinically effective fluorinated topical corticosteroid. Structurally it is 6 $\alpha$ , 9 $\alpha$ -difluoro-11 $\beta$ , 17 $\alpha$ -dihydroxy-16 $\alpha$ -methyl-21-trimethylacetoxy-1, 4-pregnadiene-3, 20-dione. Thus it is similar to such fluorinated acetonide salts of corticosteroids as fluocinolone, triamcinolone and flurandrenolone. It is a difluorinated corticosteroid in contrast to betamethasone which is monofluorinated and hydrocortisone which is non-fluorinated. Holzmann and Lachner<sup>1</sup> performed comparative tests on the effect of 4 different topical corticosteroids on human skin with 4 experimental models of inflammation of different mechanisms. They reported that Locacorten exhibits the strongest reaction-inhibiting effect in all the inflammation models and that its persistence on the skin is markedly longer than that of betamethasone valerate and fluocinolone acetonide. Gardenghi et al<sup>2</sup>, conducted studies on the percutaneous absorption of steroids and failed to demonstrate adrenocortical suppression with topical application of flumethasone. Carr et al<sup>3</sup>, however, reported that this steroid can cause some suppression if applied in sufficient amount under occlusive dressing in patients with extensive and severe dermatoses. The present study was undertaken with the object determining the efficacy of a topical cream containing 0.02% flumethasone pivalate with 0.5% neomycin sulphate in various dermatoses and in

comparison with that of 0.5% hydrocortisone acetate with 0.5% neomycin sulphate ointment.

### Material and Methods

31 patients suffering from various dermatosis comprising bilateral, symmetrical, single lesion were selected from amongst the cases attending Skin O.P.D., Willingdon Hospital, New Delhi, for this study. Of these, 19 patients were treated with various topical preparations in the past with little or no improvement. The details of preparations used could not be ascertained.

In Table I we have shown the break-up of these patients with reference to the nature of their lesions.

TABLE I

Disease	No. of cases
Contract dermatitis	20
Lichen simplex chronicus	7
Psoriasis	2
Seborrheic dermatitis	1
Granuloma annulare	1
Total	31

The patients were examined before admitting them to the trial of the preparations. They were instructed to apply flumethasone pivalate with neomycin cream twice a day on the lesion on left side and hydrocortisone acetate with neomycin ointment on the lesion on right side. The period of full

\* Locacorten<sup>(R)</sup> with neomycin-CIBA

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treatment was fixed arbitrarily at 3 weeks. In a few cases the treatment period was extended to 4 weeks. Patients were observed every week and the improvement, both subjective and objective, in the lesions was recorded. The subjective improvement was judged from the relief in pruritus as stated by the patient and also from the reduction or absence of pain of excoriation. Objectively, the improvement was judged from the reduction of erythema, vesiculation, crusting, scaliness and lichenification.

### Observations and Results

The present study covered 31 cases, of which 25 were men and 6 women. All 31 patients had bilateral pathology. Results were recorded both in terms of percentage improvement. The extent of clinical improvement following treatment with flumethasone pivalate with neomycin and hydrocortisone with neomycin was determined on the basis of percentage improvement thus: 75-100% = excellent: 50-74% = good: 25-49% = moderate: and less than 25% = unsatisfactory. The comparative therapeutic response observed with these two preparations are listed in Appendix I.

### APPENDIX I

Comparative therapeutic response with 0.02% flumethasone pivalate with neomycin and 0.5% hydrocortisone with neomycin ointment in various dermatoses

Disease	No. of Cases	Cream used	THERAPEUTIC RESPONSE				
			Excellent	Good	Moderate	Unsatisfactory	Aggravation
Contact Dermatitis	20	FMP-N	11	4	1	3	1
	20	HC-N	7	6	1	4	2
Lichen Simplex Chronicus	7	FMP-N	2	1	2	1	1
	7	HC-N	—	—	4	2	1
Seborrheic Dermatitis	1	FMP-N		1			
	1	HC-N			1		
Psoriasis	2	FMP-N			2		
	2	HC-N			2		
Granuloma Annulare	1	FMP-N				1	
	1	HC-N				1	

FMP-N = flumethasone pivalate with neomycin

HC-N = hydrocortisone with neomycin

Of 31 cases, 20 cases had contact dermatitis and the overall response in these cases was better with flumethasone pivalate with neomycin as compared to hydrocortisone with neomycin. While excellent response was observed in 11 cases with flumethasone pivalate with neomycin only 7 cases elicited excellent response with hydrocortisone with neo-

mycin. Further, in the flumethasone pivalate with neomycin treated lesions, response was good in 4 cases, moderate in one case, unsatisfactory in 3 and aggravation in one. Comparable results in hydrocortisone with neomycin treated cases were good in 6, moderate in 1, unsatisfactory in 4 and aggravation in 2.

There were 7 cases of lichen simplex chronicus. It was observed that flumethasone pivalate with neomycin cream elicited excellent response in 2 cases, good in 1, moderate in 2, unsatisfactory and aggravation in 1 each. Comparable results in hydrocortisone with neomycin ointment treated cases were excellent and/or good relief in none, moderate degree of relief in 4, unsatisfactory response in 2 and aggravation in 1 case.

There was 1 case of seborrheic dermatitis and 2 cases of psoriasis and 1 case of granuloma annulare in the series. It is obvious that the number of patients in these groups was too small to provide conclusions regarding the relative efficacy of one cream from the other in this series.

Analysis of the overall results obtained as correlated with the pretreatment severity of the disease revealed that

amongst mild and severe cases, the degree of improvement seen on lesions treated with both the preparations was almost of the same order. This is explained by the fact that the sample size in the mild and severe variety of cases was too small, viz. seven patients in each group. In the moderate cases (17 patients), however, the response with flumethasone pivalate with neomycin was better compared to that seen with hydrocortisone with neomycin: of the 17 cases followed up in this group lesions in 10 cases were completely healed when treated with flumethasone pivalate with neomycin cream. Comparatively, lesions in only 4 cases elicited a similar degree of response when treated with hydrocortisone with neomycin ointment. Initial status of disease correlated with therapeutic response to flumethasone pivalate with neomycin and hydrocortisone with neomycin are summarised in Appendix II.

## APPENDIX II

Initial status of disease correlated with therapeutic efficacy of flumethasone pivalate with neomycin and hydrocortisone with neomycin.

Degree of severity	No. of cases	Excellent		Good		Moderate		Unsatisfactory		Aggravation	
		FMP-N	HC-N	FMP-N	HC-N	FMP-N	HC-N	FMP-N	HC-N	FMP-N	HC-N
Mild	7	3	3	1	1	2	2	Nil	Nil	1	1
Moderate	17	10	4	2	3	3	5	2	4	Nil	1
Severe	7	Nil	Nil	3	2	Nil	1	3	3	1	1
Total	31	13	7	6	6	5	8	5	7	2	3

FMP-N = Flumethasone with neomycin

HC-N = Hydrocortisone with neomycin

The lesions treated with flumethasone pivalate with neomycin cream responded with excellent results in 13 cases, good in 6 cases and moderate degree of improvement in 5 cases. In the remaining cases, there was unsatisfactory response in 5 cases and aggravation in 2. The corresponding lesions on the oppo-

site sides of these patients treated with hydrocortisone with neomycin ointment responded with excellent results in 7 cases, good in 6 cases and moderate degree of relief in 8 cases. Response in 7 cases was unsatisfactory and in 3 cases there was aggravation. Overall response is listed in Appendix III.

## APPENDIX III

Final assessment in cases treated with flumethasone pivalate 0.02% with neomycin and hydrocortisone acetate 0.5% with neomycin

Degree of improvement	Flumethasone pivalate with neomycin		Hydrocortisone with neomycin	
	No. of cases	Percentage	No. of cases	Percentage
Excellent	13	42.0	7	22.5
Good	6	19.5	6	19.5
Moderate	5	16.0	8	25.5
Unsatisfactory	5	16.0	7	22.5
Aggravation	2	6.5	3	9.5

The aggravation in 2 cases was due to sensitivity to neomycin because lesions on both the sides, i. e. those treated with flumethasone pivalate with neomycin and also those treated with hydrocortisone with neomycin ointment were involved. In the 3rd case aggravation occurred only in lesions treated with hydrocortisone with neomycin and was probably due to the base of the ointment.

## Summary

31 cases suffering from various dermatoses comprising bilateral symmetrical single lesion were treated with topical application of flumethasone pivalate (Locacorten<sup>(R)</sup> cream) with neomycin on one side and hydrocortisone with neomycin ointment on the other side and the results evaluated. Flumethasone pivalate with neomycin elicited a better response compared to hydrocortisone with neomycin ointment.

## REFERENCES

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