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TOPICAL TREATMENT OF ECZEMA WITH FLUPAMESONE (FLUTENAL): A DOUBLE-BLIND COMPARISON WITH BETAMETHASONE-17-VALERATE. (METHOD OF SIMULTANEOUS SYMMETRICAL PAIRED COMPARISONS)

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ABSTRACT

In a double-blind study on 23 outpatients with simultaneous symmetrical paired lesions of moderate to severe eczema, it was demonstrated that 0.15 percent flupamesone ointment is as effective as 0.15 percent betamethasone-17-valerate in the same excipient.

INTRODUCTION

Flupamesone (9α-fluoro-11β,21-dihydroxy-16α,17α-isopropylidene-dioxy-1,4-pregnadiene-3,20-dione 4,4-methylenebis (3-methoxy-2-naphthoate)) is a synthetic corticosteroid for topical application, useful in the treatment of pruriginous and inflammatory dermatoses. Its chemical structure corresponds to two molecules of triamcinolone acetonide linked by a methembonic bridge (Fig. 1). This new compound has particularly interesting physico-chemical and therapeutic properties. Laboratory studies showed that flupamesone has an experimental corticoid potency superior to its parent compound, triamcinolone acetonide.[1] Thanks to its particular kinetics of percutaneous absorption, flupamesone remains in the epidermic layers during a prolonged period ot time, passing very slowly to the circulation.[2] This implies a superior clinical activity and the systemic effects due to topical application of fluorinated corticosteroids have not been reported.

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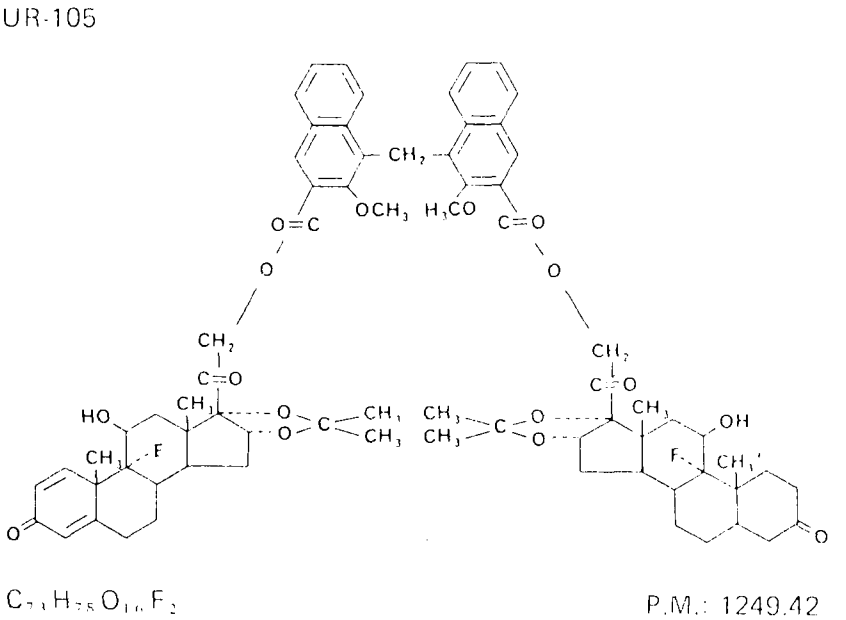
Figure 1 — *Chemical structure of flupamesone.*



Open and double-blind clinical trials had proved that 0.3 percent flupamesone ointment or cream* are highly effective and safe topical corticoid preparations.[3-7] The present study was designed to compare flupamesone with another potent corticoid, betamethasone-17-valerate.

MATERIAL AND METHOD

Twenty-nine outpatients were selected, each diagnosed as having moderate to severe eczema. Additionally, the patients exhibited bilateral lesions comparable in severity and persistence. Six patients were excluded from the analysis because a concomitant therapy had been used during the study. In fact, no local or systemic medication was permitted that could affect the dermatosis, eg, corticosteroids, antihistaminics, or antipruritic preparations. The 23 patients included in the analysis, 19 men and 4 women, ranged in age from 18 to 46 years. The original eczema was "moderate" (large thickened plaques) in 17 cases and "severe" (acute erythema with pain or itching) in 6 cases.

Each patient was provided with two 30-gm. tubes of ointment, one containing 0.15 percent flupamesone the other 0.15 percent betamethasone-17-valerate**. One tube was marked for left-side and the other for right-side application. The identity of these tubes was unknown by the clinician.

* Flutenal cream/ointment, product of J. Uriach & Cía. Laboratories, Bruch, 49. Barcelona 9. Spain.

** Material for study was supplied by J. Uriach & Cía. Laboratories. The ointment base was identical for both preparations: plastibase®.

Ointments were applied twice daily and the patients were re-examined after 1 and 2 weeks of treatment and their clinical condition assessed as *excellent*, *good*, *fair* or *poor*. Objective criteria for judging therapeutic response included decreases in erythema, scaling, thickening, and edema. Subjective criteria were decreases in pruritus and burning.

After a clinical pharmacologist of J. Uriach & Cía. Laboratories had reviewed the case reports for completeness and compliance with the protocol, the code used for the tubes was broken and the results were tabulated. Comparative judgements between the responses were recorded as *superior* when a discernible difference in response was denoted, as *equal response* when there was a non-observable difference, and *neither* when none of both sides had responded during the observation period.

RESULTS

Table I shows the response of lesions after 1 and 2 weeks treatment. In the first evaluation, flupamesone was superior in 8 of 23 cases and betamethasone valerate was superior in 7 cases; the two drugs were judged equal in effectiveness in 8 cases. In no case were the drugs ineffective. The corresponding figures after two weeks of treatment were: flupamesone superior in 5 cases; betamethasone valerate in 6 cases; drugs equally effective in 12 cases. The differences between the therapeutical activities of the two corticoids were not statistically significant.

Once the treatment period was ended, the evaluation of effectiveness showed excellent or good responses to flupamesone in 18 of 23 cases. The

Table I — *Comparative clinical responses**

Time	No. of Patients Evaluated	Flupamesone Superior	Betamethasone Valerate Superior	Drugs Equal	Neither Effective
Week 1	23	8	7	8	—
Week 2	23	5	6	12	—

* Differences between flupamesone and betamethasone-17-valerate were not statistically significant.

degree of therapeutical activity for this new topical corticoid was the same as for betamethasone valerate (Table II).

Seven patients commented that they preferred the "right" ointment

Table II — *State of lesions after two weeks of treatment**

	Excellent	Good	Fair	Poor
Flupamesone	9	9	5	—
Betamethasone-17-valerate	10	8	5	—

* Differences between flupamesone and betamethasone-17-valerate were not statistically significant.

(flupamesone) and other seven patients the "left" one (betamethasone valerate); the remaining nine patients did not express any preference.

Two patients with initial erythema and vesiculation on both body sides presented only a slight improvement, erythema and vesiculation persisting during the treatment. There were no other side effects with the two preparations assayed.

CONCLUSION

In a double-blind comparative study, 0.15 percent flupamesone (Flutenal ointment) proved to be equally as effective as 0.15 percent betamethasone-17-valerate in the topical treatment of severe and moderate eczema. No side effects due to the preparations were noted.

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