FLUOCINOLONE ACETONIDE.

A New Steroid Preparation for Topical Use.

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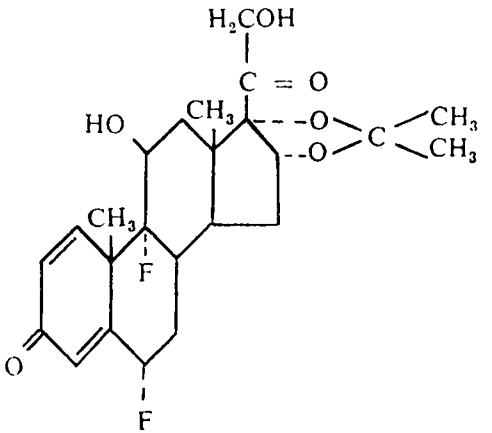
Fluocinolone acetonide is a new steroid preparation discovered by Syntex and marketed in this country under the name of "Synalar" by Imperial Chemical Industries.

Robinson (1961) reported good results from this preparation in a trial of a large number of patients in the U.S.A. The substance is remarkable in that it is reported in a personal communication quoted by Robinson to be of little or no value on dermatological conditions when given orally but is very effective when applied locally in high dilution. Robinson used two preparations, a cream and a lotion, each containing the steroid in a strength of 0·025%. In his article he gives details of the bases used.

The full chemical name of this substance is 6 alpha, 9 alpha-difluoro-16 alpha-hydroxyprednisolone-16, 17-acetonide. Its structural formula is



It will be noted that the molecule contains two fluorine atoms compared to the one fluorine atom of triamcinolone.

Investigation.

A supply of the cream in the same water miscible base as used by Robinson was made available to us for clinical trial. Preliminary tests indicated that it showed great promise and so a double blind trial was arranged using as a control 1% hydrocortisone in the same base. The patients were given the preparations in random order and they were dispensed by the pharmacists. Neither patient nor clinician knew which preparation had been dispensed until the end of the trial. When the

patient returned for review there was a switch to the alternative preparation. Later the patient was asked to express an opinion as to which preparation he preferred. It was not possible to give both preparations to every patient, either because the lesions had entirely or almost entirely subsided, or because the response to the first preparation was of such a nature that it was not considered wise to use the other apparently identical material.

Out of 31 patients who entered the trial, 15 were given both preparations and of these 10 expressed a preference for 0·025% fluocinolone acetonide, none for 1% hydrocortisone and 5 were unable to decide which preparation they preferred. These figures give a highly significant preference for fluocinolone acetonide. All patients had some form of eczema or dermatitis and most had shown only poor response to earlier treatments. As with other topical steroid preparations relapse was liable to occur when treatment was discontinued.

Twenty-five other patients have been treated and in the great majority of cases the response has been highly satisfactory. The rate of improvement has perhaps been the most pleasing feature of this treatment. In six cases the cream has caused some irritation or stinging when applied but in only one case was the condition objectively aggravated by it. It seems probable that any irritation which is caused is due to the base, as two patients using 1% hydrocortisone reported this effect. The base may be too drying for some patients and in these cases a greasy base would have been preferable.

Discussion.

It seems probable that fluocinolone acetonide will be a very valuable preparation as a local application in a wide range of dermatological conditions of an eczematous nature. Its effects in a strength of 0·025% are very rapid and it is possible that it will be effective in even higher dilution. Although the water miscible base does not suit every patient, this defect should be remedied when a greasy preparation becomes available.

Summary.

A controlled clinical trial using 0·025% fluocinolone acetonide in a water miscible cream compared with 1% hydrocortisone in the same base is reported. The results showed a significant preference for the new preparation.

Our thanks are due to the Pharmacists at Westminster Hospital for their co-operation in this trial and to Dr. C. C. Downie of the Pharmaceutical Division of Imperial Chemical Industries Ltd., who introduced us to the new preparation and made supplies and control material available to us.

Reference.

Robinson, H. M. (1961) *Arch. Derm., Chicago*, **83**, 149.