United States Patent Office 3,043,745 Patented July 10, 1962

3,043,745

ALLANTOIN AND COAL TAR EXTRACT COMPOSITION AND TREATMENT OF PSORIASIS

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No Drawing. Filed Dec. 11, 1959, Ser. No. 858,870
10 Claims. (Cl. 167—58)

The present invention relates to an improved method for the treatment of psoriasis. This application is a continuation-in-part of co-pending application Serial No. 714,482, filed February 11, 1958, now abandoned.

Psoriasis is a highly important dermatosis. It has an incidence of between 1% and 2% of the total population, and its lesions are of recurrent nature and usually very resistant to therapy. The lesions are usually numerous and are characteristically silvery gray scaling papulas or plaques with an underlying redness which most frequently occur in the scalp, elbows, knees and lumbosacral region. The etiology of the disease is at present completely unknown, although it is non-infectious and believed to be the result of a metabolic deficiency.

There is at present no known permanent cure for psoriasis, although there are several treatments which are transitory and only occasionally effective, completely losing their usefulness after repeated application. The general effect of these treatments is either merely to physically cover the afflicted areas or to cause a peeling of the skin. Typical of these treatments, which requires from ten to thirty days, is the application of crude coal tar ointment to the affected area three times daily, daily ultraviolet exposure to the point of producing a transient erythema followed by prolonged tub baths. It is thus apparent that there is no satisfactory, simple and convenient method for the treatment of psoriasis.

It is, therefore, a principal object of the present invention to provide an improved method for the treatment of psoriasis.

Another object of the present invention is to provide an improved method for the treatment of psoriasis which does not unduly incapacitate or inconvenience the patient.

Still another object of the present invention is to provide an improved simple and inexpensive method for the treatment of psoriasis.

The present invention is based on the discovery that the topical application to a psoriasis-afflicted area of a medication containing a predetermined concentration of allantoin and coal tar extract is followed by a relatively prompt disappearance of the gross scaling followed by a radical reduction in or the disappearance of the redness and lesions. As long as the medication is applied, the characteristic symptoms of the psoriasis will not return. The treatment may be safely continued until the disease completely subsides. The allantoin should be present in concentrations exceeding ½% and preferably in excess of 1% and more particularly in concentrations of between 2% and 10% and the coal tar extract should be present in a concentration exceeding 1% and preferably should be between 1% and 10%.

Scaling is constantly present and occuring in the normal epidermis but the size of the scales are so minute that they are not usually observable or unsightly. In the case of psoriasis, however, the scales are gross and unsightly. A chemical analysis of the psoriasis scales as compared to the normal epidermis scale indicates that the water soluble fraction of the psoriasis scale is low in its free amino nitrogen content and high in its sulfhydryl content. The application of the allantoin to the psoriasis-afflicted area results in the epidermis returning, at least superficially, to its normal scaling activity. It is believed that under normal scaling conditions the protein depolymerizes

to form minute scales and that the necessary depolymerization is absent in the case of psoriasis. It is further believed that the application of the allantoin to the afflicted areas promotes the necessary depolymerization so that the resulting scales are of normal minute size. The mechanisms and function of the coal tar extract is not clearly understood, but when used with the allantoin there is a pronounced cooperatively produced activity insofar as the treaatment of psoriasis is concerned.

A specific example of a lotion which has proven to be highly effective is as follows.

Ingredients:	Percentage by weight
Polyethylene glycol monostearate "400," U.S.P.	2.5
Isopropyl palmitate	2.5
Stearic acid, N.F	3.0
Propylene glycol, U.S.P	10.0
Coal tar extract	5.0
Allantoin	2.0
Water (demineralized)	75.0
Perfume (if desired), q.s.	

The lotion is prepared by mixing the polyethylene glycol monostearate, isopropyl palmitate, stearic acid, N.F., propylene glycol and coal tar extract (liquor carbonis detergens) in a suitable jacketed kettle. The mixture is then heated to 80° C. with stirring until all the ingredients are melted and then the water, at 80° C., is added and mixing continued until an emulsion is obtained, the mixing time being approximately thirty minutes. The emulsion is then cooled to 40° C. and the allantoin added with gentle agitation, the mixing being continued until the lotion has cooled to room temperature. The allantoin should preferably be in solution in the lotion or in the form of a fine suspension in which the allantoin particle size averages about 200 microns or smaller.

The allantoin should constitute at least ½% by weight of the lotion and preferably between 2% and 10% by weight. The coal tar extract should be present in amounts of between 1% and 10% by weight of the lotion. The amounts of polyethylene glycol monostearate, isopropyl palmitate, stearic acid and propylene glycol may be varied within ranges which will produce a stable lotion with the allantoin at the above concentration and in solution or in a fine uniform colloidal dispersion. Furthermore, suitable substitutes may be employed in place of some of the ingredients, for example, polyethylene glycol monostearate of higher molecular weight my be substituted. Other materials such as cetyl alcohol, lanolin or lanolin alcohols, or other emulsified fatty acids may be used. It should, of course, be noted that promptly following the application of the medication most of the water evaporates leaving the allantoin, coal tar extract and other ingredients present in correspondingly greater concentrations.

The lotion specifically set forth above has been employed clinically and has proven unexpectedly and remarkably effective. In one set of tests, the lotion was topically applied as a thin layer to the psoriasis-afflicted areas of thirty-two patients between two and four times daily. In all cases, a prompt clearing of the typical psoriatic scale occurred during the first week of treatment. In from one to four weeks the underlying redness was either materially lessened or completely disappeared so that the skin assumed its normal appearance. No peeling accompanied the treatment. In four cases, the psoriasis completely cleared and there was no recurrence for two months after the cessation of the treatment. Of the thirty-two cases, sixteen were concurrently given supplementary ultraviolet light treatment, but there was no difference in their response as compared to those who were treated with the lotion alone. Some patients afflicted with neurodermititis, the symptoms of which are some-

times similar to those of psoriasis, were subjected to the same treatment with the lotion but showed no response whatsoever.

In another set of clinical tests, on twenty-six different patients having psoriasis, the same treatment as described above was followed. In all cases there was a prompt clearance of the scaling and a steady gradual improvement of the red indurated skin surface. Both sets of clinical tests conclusively demonstrated the radical superiority of the present improved therapy over any therapy previously employed.

The concurrent use of the allantoin and the coal tar extract exhibits pronounced cooperatively produced activity. A group of patients were each contra-laterally treated with the above described ointment containing both the coal tar extract and the allantoin, a corresponding ointment in which the allantoin was omitted, and a corresponding ointment in which the coal tar extract was omitted. In each instance, the patient initially had a rather severe case of psoriasis. In each case, the area treated by the ointment containing the coal tar extract and the allantoin subsequently exhibited a complete absence of skin lesions or only diminished scaling and mild pruritis; the areas treated with the ointment lacking the allantoin subsequently exhibited at best only a slight improvement and in some cases an aggregation of the symptoms, and the areas treated by the ointment lacking the coal tar extract, on the average, showed no improveemnt whatsoever.

While the allantoin coal tar extract medication was applied to the afflicted areas in the form of a lotion, it should be noted that it may be applied in other forms of vehicles such as, for example, a salve or ointment or the like, the preparation of which, within the limits above set forth, presents no particular difficulty.

Having now described my invention, what I claim and desire to secure by Letters Patent is:

1. The method of treating psoriasis comprising applying to the psoriasis-afflicted area a medicament containing a cooperating mixture of allantoin in a concentration by weight exceeding ½% and a coal tar extract in a concentration exceeding 1% by weight.

2. The method of treating psoriasis in accordance with claim 1, wherein the concentration of the allantoin is between 2% and 10%.

3. The method of treating psoriasis in accordance with claim 1, wherein said coal tar extract is at a concentration between 1% and 10% by weight.

4. The method of treating psoriasis in accordance with claim 2, wherein said coal tar extract is at a concentration between 1% and 10% by weight.

5. An improved medicament for the treatment of psoriasis comprising a composition applicable to a psoriasis-afflicted area and including a cooperating mixture of at least ½% by weight of allantoin and at least 1% by weight of coal tar extract.

6. An improved medicament in accordance with claim 5, wherein said allantoin constitutes between 2% and 10% by weight of the medicament.

7. An improved medicament in accordance with claim 5, wherein said coal tar extract constitutes between 1% and 10% by weight of said medicament.

8. An improved medicament in accordance with claim 5, wherein said allantoin constitutes between 2% and 10% by weight and said coal tar extract between 1% and 10% by weight of said medicament.

9. An improved medicament in accordance with claim 8, including water and an emulsifying agent.

10. An improved medicament for the treatment of psoriasis comprising the following ingredients in substantially the designated percentages by weight:

	Percent
Polyethylene glycol monostearate "400"	2.5
Isopropyl palmitate	2.5
Stearic acid	3.0
Propylene glycol	10.0
Coal tar extract	5.0
Allantoin	2.0
Water	75.0

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