

was then treated with a 10% (w/w) formulation including vehicle and the aminoguanidine prepared according to Example 1. After 4 days of treatment, the scaly lesions and the raised plaques went away (see FIGS. 1B, 2B and 3B), and the patient reported that the itching stopped.

### Example 3

#### Clinical Study

The purpose of this study is to compare the treatment with 10% (w/w) aminoguanidine of psoriatic plaques on one side of the body with a treatment with vehicle alone of a plaque on the contralateral side of the body.

#### Study Population

10–20 adult male/female patients of 18 years of age or older with chronic, plaque type psoriasis, who are not currently on any systemic treatment for psoriasis are selected for the study. The following patients are excluded from the study:

Patients taking or using systemic anti-inflammatory medication (e.g. corticosteroids), or who have taken or used them in the previous four weeks.

Patients using or who have used systemic antipsoriasis treatment (e.g. methotrexate) within the previous four weeks.

Patients using immunosuppressive drugs.

Patients using OTC/Rx topical drugs to the areas to be treated (test sites) during the past 1 week. Patients are allowed to use topical prescription drugs on areas of the body other than the selected test sites.

Patients who are known to be HIV positive.

Pregnancy.

#### Test Materials

Placebo: Nivea® creme alone

Active Cream: Nivea® creme containing 10% (w/w) aminoguanidine.

The patients selected for the study are instructed to apply active cream 1–3 times a day to plaques on one side of the body and, if possible, base cream to a plaque on the contralateral side of the body. The applications are performed mornings, afternoons and evenings for a period of 4 weeks. The creams are labeled A and B. Neither the panelist nor the principal investigator knows the exact nature of the creams applied. The areas of the body of different patients receiving either cream A or B are selected by random rotation. Twice a week, the patients return to the laboratory for a dermatological examination and possible photographs of the treatment sites. In addition, photographs are taken at the first and last visits. The patients are asked to maintain a diary to evaluate both estetic qualities of the cream and subjective symptoms (i.e., itching, stinging, burning, amount scales).

#### Evaluation

Resolution of the plaque(s) is monitored visually and with photography. The visual scoring is done using a modified Psoriasis Area and Severity Index (PASI) score. The individual with psoriasis is seen in the laboratory twice a week. The patients are scored at a minimum on Day 1 (baseline), at the end of week two (Day 14) and week four (Day 28). If dramatic improvement occurs earlier than Day 14, the patients are scored and photographed earlier.

The above examples demonstrate methods of preparing a topical formulation of aminoguanidine. The examples also demonstrate that treatment of psoriasis with an aminoguanidine formulation (10% w/w) alleviates psoriatic symptoms.

All publications and patent applications mentioned in this specification are indicative of the level of skill of those skilled in the art to which this invention pertains. All publications and patent applications are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

The invention now having been fully described, it will be apparent to one of ordinary skill in the art that many changes and modifications can be made thereto without departing from the spirit or scope of the appended claims.

What is claimed is:

1. A method for treating psoriasis, sand method comprising:

contacting a psoriatic lesion with an aminoguanidine composition containing between 1–30 weight percent aminoguanidine in a carrier for topical application, in an amount sufficient to alleviate at least one symptom selected from the group consisting of reducing size, thickness or scales of a psoriatic lesion, reducing erythema, decreasing itching and decreasing induration.

2. The method according to claim 1, wherein said composition is a cream, an ointment, a lotion, a gel, or a patch.

3. A composition comprising:

aminoguanidine in a concentration about 1–30% by weight of said composition, effective to alleviate at least one symptom of a skin disease caused by or associated with hyperproliferation of keratinocytes, when administered to a mammal suffering from said skin disease, wherein said composition (i) does not include an active thiol agent, and (ii) is in the form of a stick, an oil, an ointment, a cream, a gel, a lotion, a paste, or a patch.

4. The composition according to claim 3, wherein said aminoguanidine concentration is about 2–20% by weight of said composition.

5. The composition according to claim 3, said composition further comprising a skin penetration enhancer.

6. The pharmaceutical composition according to claim 5, wherein said carrier is an oil-in-water emulsion.

\* \* \* \* \*