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(54) Title: TOPICAL SKIN TREATMENT KITS

(57) Abstract: This invention relates to benzoyl peroxide products for skin treatment, and more particularly to a kit containing a benzoyl peroxide product and a topical moisturizing product. In one embodiment the kit contains BenzaClin® brand clindamycin-benzoyl peroxide gel and Viscontour® brand hyaluronic acid serum.



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TOPICAL SKIN TREATMENT KITS

FIELD OF THE INVENTION

5 This invention relates to benzoyl peroxide products for skin treatment, and more particularly to a kit containing a benzoyl peroxide product and a topical moisturizing product.

BACKGROUND OF THE INVENTION

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Acne is an inflammatory disease which is very common at puberty and which occurs in skin areas where sebaceous glands are largest, most numerous, and most active. In its milder forms, acne is a superficial disorder which is evidenced by slight, spotty irritations, and which can be treated satisfactorily by ordinary skin hygiene. However, pilosebaceous follicles occur and result in the formation of pustules, infected cysts and, in extreme cases, canalizing inflamed and infected sacs, which may become extensive and leave permanent, disfiguring scars.

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Zhen et al, J. Drugs Dermatol, Aug. 2007, 6(8): 810-6, indicates that topical therapies effective in treatment of acne, may be associated with local effects, such as irritation and dryness. In comparison, subjects treated with an OTC moisturizer (Nivea brand cream) exhibited skin hydration.

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Among the topical anti-acne therapies are preparations which include a peroxide, such as benzoyl peroxide, or a combination of a peroxide and an antibiotic, such as an antibiotic of the lincomycin family, are disclosed in US Patent Nos. 5,466,028, 5,767,098 and 6,013,637, all of which are incorporated herein by reference. However, benzoyl peroxide has been found to have a natural drying effect.

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SUMMARY OF THE INVENTION

In accordance with the present invention, it has been found that a moisturizer can be useful to overcome the drying effects of benzoyl peroxide preparations. These local adverse effects of benzoyl peroxide may become severe, which may reduce patient

adherence or require discontinuation, and thus compromising treatment efficacy.

Increasing the hydration of the skin with a moisturizer can effectively reduce the local adverse effects caused by the acne treatment, thereby rendering a more successful treatment outcome.

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In accordance with the present invention, there is provided a kit comprising a topical acne medication containing benzoyl peroxide and a separate hydration agent for moisturizing the skin.

10 In a particular embodiment, the topical acne medication comprises benzoyl peroxide and an antibiotic of the lincomycin family as described in the above-cited US Patent Nos. 5,466,028, 5,767,098 and 6,013,637.

In a further embodiment, the hydration agent comprises a hyaluronic acid formulation.

15 A particular hyaluronic acid formulation suitable for use in the present invention is sold under the trademark Viscontour® Serum.

DETAILED DESCRIPTION OF THE INVENTION

20 The kit of the present invention includes a topical acne medication containing benzoyl peroxide. In a particular embodiment, the acne medication comprising benzoyl peroxide in combination with a topically active antibiotic.

One acne medication suitable for use in the present invention comprises benzoyl
25 peroxide and an antibiotic of the lincomycin family. A particularly suitable lincomycin antibiotic for use in the acne medication is clindamycin.

A topical gel comprising clindamycin (1%) as clindamycin phosphate and benzoyl peroxide (5%) is commercially available, and is sold under the name BenzaClin®
30 topical gel. BenzaClin® topical gel contains clindamycin phosphate, (7(S)-chloro-7-deoxylincomycin-2-phosphate). Clindamycin phosphate is a water soluble ester of the semisynthetic antibiotic produced by a 7(S)-chloro-substitution of the 7(R)-hydroxyl group of the parent antibiotic lincomycin. Chemically, clindamycin

phosphate is (C₁₈H₃₄ClN₂O₈PS). Clindamycin phosphate has molecular weight of 504.97 and its chemical name is methyl 7-chloro-6,7,8-trideoxy-6-(1-methyl-trans- 4-propyl-L-2-pyrrolidinecarboxamido)-1-thio-L- threo-alpha-D- galacto-octopyranoside 2-(dihydrogen phosphate).

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BenzaClin® topical gel also contains benzoyl peroxide, for topical use. Chemically, benzoyl peroxide is (C₁₄H₁₀O₄). Benzoyl peroxide has a molecular weight of 242.23. Each gram of BenzaClin® topical gel contains, as dispensed, 10 mg (1%) clindamycin as phosphate and 50 mg (5%) benzoyl peroxide in a base of carbomer, sodium hydroxide, dioctyl sodium sulfosuccinate, and purified water.

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Viscontour® serum is a topical hyaluronic acid for skin hydration. It contains water, sodium hyaluronate, sodium chloride, sodium monohydrogenphosphate and sodium dihydrogenphosphate. It is distributed in sterile single-use 0.03 fluid ounce ampoules.

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EXAMPLE

A kit is assembled comprising a jar of BenzaClin® clindamycin phosphate/benzoyl peroxide topical gel and one or more ampoules of Viscontour® hyaluronic acid serum. The clindamycin phosphate/benzoyl peroxide gel is applied to a patient's skin, and then the hyaluronic serum is applied.

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CLAIMS

We claim:

- 5 1. A kit comprising separate containers of a topical medication comprising benzoyl peroxide in a pharmaceutically acceptable carrier and a hydrating agent.
2. The kit of claim 1 wherein the topical medication also contains an antibiotic.
- 10 3. The kit of claim 2 wherein the antibiotic is clindamycin or a pharmaceutically acceptable salt or ester thereof.
4. The kit of claim 3 wherein the topical medication comprises about 0.01 to about 10 weight percent antibiotic and about 0.1 to about 30 weight percent benzoyl
15 peroxide.
5. The kit of claim 4 wherein the antibiotic is clindamycin phosphate.
6. The kit of claim 5 wherein the topical medication comprises about 1 weight
20 percent clindamycin phosphate and about 5 weight percent benzoyl peroxide.
7. The kit of any of claims 1 to 6 wherein the hydrating agent comprises a hyaluronic acid in a pharmaceutically acceptable carrier.
- 25 8. The kit of claim 7 wherein the hydrating agent comprises water, sodium hyaluronate, sodium chloride, sodium monohydrogenphosphate and sodium dihydrogenphosphate.
9. The kit of claim 8 wherein the hydrating agent is Viscontour® brand hyaluronic
30 acid serum.
10. The kit of claim 9 wherein the topical medication is BenzaClin® brand clindamycin-benzoyl peroxide gel.

11. A method of treating a skin disorder or condition in a patient, the method comprising topically administering a medication comprising benzoyl peroxide in a pharmaceutically acceptable carrier, and applying a separate hydrating agent to the skin.
12. The method of claim 11 wherein the medication is topically administered to the skin first and the hydrating agent is applied to the skin second.
13. The method of claim 11 wherein the medication further comprises an antibiotic.
14. The method of claim 13 wherein said antibiotic is clindamycin or a pharmaceutically acceptable salt or ester thereof.
15. The method of claim 14 wherein the antibiotic is clindamycin phosphate.
16. The method of any one of claims 11 to 15 wherein the hydrating agent comprises a hyaluronic acid in a pharmaceutically acceptable carrier.
17. The method of any one of claims 11 to 16 wherein the skin disorder is acne.