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(54) **DERMATOLOGICAL COMPOSITIONS COMPRISING RETINOIDS, DISPERSED BENZOYL PEROXIDE AND CARRAGEENANS**

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(57) **ABSTRACT**

Dermatological compositions containing, in a physiologically acceptable medium, at least one retinoid, dispersed benzoyl peroxide and at least one gelling agent of the family of the carrageenans, are useful for treating dermatological conditions and afflictions linked to disorders of cell differentiation and/or proliferation and/or keratinization, notably for treating acne vulgaris.

DERMATOLOGICAL COMPOSITIONS COMPRISING RETINOIDS, DISPERSED BENZOYL PEROXIDE AND CARRAGEENANS

CROSS-REFERENCE TO PRIORITY/PCT APPLICATIONS

[0001] This application claims priority under 35 U.S.C. §119 of FR 0850131, filed Jan. 10, 2008, and is a continuation of PCT/FR 2009/050040, filed Jan. 12, 2009 and designating the United States (published in the French language on Jul. 30, 2009 as WO 2009/092954 A1; the title and abstract were also published in English), each hereby expressly incorporated by reference in its entirety and each assigned to the assignee hereof.

BACKGROUND OF THE INVENTION

[0002] 1. Technical Field of the Invention

[0003] The present invention relates to dermatological compositions comprising, formulated into a physiologically acceptable medium, at least one retinoid, dispersed benzoyl peroxide and at least one carrageenan.

[0004] 2. Description of Background and/or Related and/or Prior Art

[0005] The administration of several categories of active principles is a therapeutic tool to which recourse is frequently had, in particular in the treatment of dermatological disorders.

[0006] Specifically, it is known to administer peroxides, vitamins D and retinoids in the topical treatment of various pathologies related to the skin or mucous membranes, in particular acne.

[0007] The combination of several local treatments (antibiotics, retinoids, peroxides, zinc) is also employed in dermatology to make it possible to enhance the effectiveness of the active principles and to reduce their toxicity (Cunliffe W. J., J. Dermatol. Treat., 2000, 11 (Suppl. 2), S13-S14).

[0008] The multiple application of different dermatological products may be rather burdensome and demanding for the patient.

[0009] The interest in attempting to obtain a novel treatment which is effective with regard to dermatological conditions in a stable composition which offers a good cosmetic quality, which makes possible a single application and which makes possible administration which is agreeable to the patient is thus understood.

[0010] There is nothing among this range of therapies provided to one skilled in the art which would encourage him to combine, in the same composition, benzoyl peroxide, a retinoid and several gelling agents.

[0011] This is because the formulation of such a composition presents several problems.

[0012] First of all, the effectiveness of the benzoyl peroxide is related to its decomposition when it is brought into contact with the skin. This is because it is the oxidizing properties of the free radicals produced during this decomposition which result in the desired effect. Consequently, to maintain the optimum effectiveness of the benzoyl peroxide, it is important to prevent it from decomposing before use, that is to say during storage. In point of fact, benzoyl peroxide is an unstable chemical compound, which makes it difficult to formulate it into finished products.

[0013] The solubility and the stability of benzoyl peroxide have been studied by Chellquist et al. in ethanol, propylene glycol and various mixtures of polyethylene glycol 400 (PEG 400) and water (Chellquist E. M. and Gorman W. G., Pharm. Res., 1992, Vol. 9, 1341-1346). It turns out that benzoyl peroxide is particularly soluble in PEG 400 and ethanol.

[0014] This document furthermore specifies that the stability of benzoyl peroxide is strongly influenced by the chemical composition of the formulation and by the storage temperature. Benzoyl peroxide is highly reactive and decomposes in solution at low temperature due to the instability of its peroxide bond.

[0015] The authors thus determine that benzoyl peroxide in solution decomposes more or less rapidly in all the solvents studied according to the type of solvent and its concentration.

[0016] The decomposition times of benzoyl peroxide in PEG 400 (0.5 mg/g), in ethanol and in propylene glycol are 1.4, 29 and 53 days respectively at 40° C. Such a decomposition does not make possible the formulation of a product intended for sale.

[0017] Furthermore, it is known that benzoyl peroxide is more stable in water and propylene glycol when it is in suspension (i.e., in the dispersed form), since it is not decomposed after storing for 90 days in these solvents.

[0018] Thus, to limit the problem of rapid instability of benzoyl peroxide in solution, it has proven to be advantageous to formulate benzoyl peroxide in the dispersed form.

[0019] However, this type of formulation is not completely satisfactory insofar as the benzoyl peroxide is still found to be decomposed in the finished product.

[0020] Another difficulty to be overcome in the formulation of a composition comprising both benzoyl peroxide and a retinoid is that the majority of retinoids are particularly sensitive to natural oxidation, to visible light and ultraviolet radiation. As benzoyl peroxide is a strong oxidizing agent, the chemical compatibility of these two compounds in one and the same formulation presents numerous problems of stability from the physical and chemical viewpoint.

[0021] A stability study was carried out on two retinoids by combining two commercial products, one comprising a retinoid (tretinoin or adapalene) and the second based on benzoyl peroxide (B. Martin et al., Br. J. Dermatol., (1998) 139, (suppl. 52), 8-11).

[0022] The presence of benzoyl peroxide in the formulation causes very rapid decomposition of the oxidation-sensitive retinoids: 50% of the tretinoin is measured as decomposing in 2 hours and 95% in 24 hours. In the composition comprising adapalene as retinoid, no decomposition of the adapalene was measured during 24 hours.

[0023] This study confirms that benzoyl peroxide is decomposed and decomposes oxidation-sensitive retinoids over time by gradually releasing benzoic acid in finished products.

[0024] In point of fact, it is clear that the decomposition of benzoyl peroxide and retinoids is not desirable insofar as it is harmful to the effectiveness of the composition in which they are present.

[0025] Nothing thus prompted the combining of these two active agents to obtain a stable composition of gel or emulsion type, it being known that it was conventionally recognized that the presence of benzoyl peroxide chemically and physically destabilized compositions of these types.

[0026] In particular, the formulation as a gel of benzoyl peroxide and a retinoid is advantageous for topical treatments, such as that of acne, as it avoids in particular leaving a greasy feel remaining on the skin.

[0027] More specifically, the term "gel" means a system comprising at least one thermodynamically stable phase (in general one or two phases) resulting from the coagulation as a three-dimensional network of a colloidal solution. More precisely, an aqueous gel corresponds to a composition comprising, in an aqueous phase, a viscoelastic mass formed from colloidal suspensions (carrageenan or combination of a carrageenan with another gelling agent).

[0028] In particular, the formulation as a "light" emulsion of benzoyl peroxide and a retinoid is advantageous for topical treatments, such as that of acne, as, in the case of a "light" emulsion, it contributes emollience while avoiding leaving an excessively greasy feel remaining on the skin.

[0029] "Light" emulsion means an emulsion comprising a low proportion of fatty phase, the aqueous phase remaining predominant. An emulsion is a system comprising two fluids which are insoluble or only slightly soluble in one another, and in which one of the fluids is dispersed in the other as microscopic particles. Preferably, the emulsions used comprise or do not comprise at least one emulsifier, a polar hydrophilic phase, preferably aqueous phase, and a nonpolar fatty phase. Preferably, they are provided in the form of "oil-in-water" (O/W) or "water-in-oil" (W/O) emulsions.

[0030] In point of fact, another difficulty to be overcome in the formulation of a composition comprising in particular benzoyl peroxide, when it occurs in the gel or emulsion form, is that the gelling agents of the aqueous phase are destabilized by the benzoic acid released during the decomposition of the benzoyl peroxide.

[0031] Specifically, the gelling agents of the aqueous phase most commonly used with benzoyl peroxide are acrylic acid polymers (carbomer).

[0032] In point of fact, the use of carbomers in compositions of aqueous gel type does not provide good results in terms of chemical stability of the benzoyl peroxide and in terms of rheological stability. As described by Bollinger (Bollinger, Journal of Pharmaceutical Science, 1977, Vol. 5), a loss of 5 to 20% of benzoyl peroxide after 2 months at 40° C., depending on the neutralizing agent of the carbomer used, was observed. Furthermore, the release of benzoic acid brings about depolymerization of the carbomers, giving a fall in viscosity which may bring about phase separation.

[0033] This instability of benzoyl peroxide gels (as such or as gelled aqueous phase of an emulsion) is thus harmful to their effectiveness and to their cosmetic quality.

[0034] Furthermore, a finished product, in particular when it concerns pharmaceutical or cosmetic compositions, must maintain, throughout its lifetime, precise physicochemical criteria which make it possible to guarantee its pharmaceutical and cosmetic quality. Among these criteria, it is necessary for the rheological properties to be retained. They define the behavior and the texture of the composition during application but also the properties of release of the active principle [SFSTP Commission report 1998] and the homogeneity of the product when the active principles are present therein in the dispersed state.

[0035] Need thus exists for a physically and chemically stable composition of gel or emulsion type comprising benzoyl peroxide and a retinoid.

SUMMARY OF THE INVENTION

[0036] Dermatological compositions of gel and emulsion type have now been developed which meet this need, which comprise dispersed benzoyl peroxide in the free or encapsulated form, at least one retinoid and at least one carrageenan, which have good physical stability, that is to say which do not exhibit a drop in viscosity over time and in particular at ambient temperature, and which maintain good chemical stability of the two active principles (benzoyl peroxide and retinoid). In particular, decomposition of the active principles over time and/or at ambient temperature is not observed.

[0037] The present invention thus features compositions comprising, formulated into the same physiologically acceptable medium:

[0038] at least one retinoid,

[0039] benzoyl peroxide,

[0040] at least one gelling agent of the family of the carrageenans, the said benzoyl peroxide and/or the said at least one retinoid preferably being in a form dispersed in the said composition.

DETAILED DESCRIPTION OF BEST MODE AND SPECIFIC/PREFERRED EMBODIMENTS OF THE INVENTION

[0041] According to a preferred embodiment, the composition is a combination, the active principles of which are combined at fixed doses within one and the same vehicle (single formulation) which delivers them together. Preferably, the pharmaceutical composition in the form of a fixed combination is a gel; in this case, the two active principles are dispersed and intimately mixed during formulation in one and the same vehicle, which delivers them together when the gel is applied.

[0042] The term "physiologically acceptable medium" means a medium compatible with the skin, mucous membranes and superficial body growths.

[0043] Preferably, the pharmaceutical composition is useful for a single topical application daily.

[0044] The term "active principle in the dispersed form according to the invention" means an active principle in the form of solid particles suspended in a given vehicle. Such particles have in particular a size of greater than 10 μm.

[0045] Advantageously, the particle size of the retinoid and of the benzoyl peroxide is such that at least 80% by number of the particles and preferably at least 90% by number of the particles have a diameter of less than 25 μm and at least 99% by number of the particles have a diameter of less than 100 μm.

[0046] The compositions according to the invention comprise at least one retinoid. The term "retinoid" means any compound which binds to RAR and/or RXR receptors. Preferably, the retinoid is a compound selected from the family of the benzonaphthalene retinoids (also known as naphthoic acid compounds), such as described in EP-0199636, in particular:

[0047] 6-(3-methylphenyl)-2-naphthoic acid and its methyl ester,

[0048] 6-(4-(tert-butyl)phenyl)-2-naphthoic acid and its methyl ester,

[0049] 6-(3-(tert-butyl)phenyl)-2-naphthoic acid and its methyl ester,

[0050] 6-(3,4-dimethoxyphenyl)-2-naphthoic acid and its methyl ester,

[0051] 6-(p-(1-adamantylthio)phenyl)-2-naphthoic acid and its methyl ester,

[0052] 6-(3-(1-adamantyl)-4-methoxyphenyl)-2-naphthoic acid (adapalene) and its methyl ester,

[0053] the methyl ester of 6-[3-(1-adamantyl)-4-(tert-butyldimethylsilyloxy)phenyl]-2-naphthoic acid,

[0054] the methyl ester of 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthoic acid,

[0055] 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthoic acid,

[0056] the methyl ester of 6-[3-(1-adamantyl)-4-decyloxyphenyl]-2-naphthoic acid,

[0057] 6-[3-(1-adamantyl)-4-decyloxyphenyl]-2-naphthoic acid,

[0058] the methyl ester of 6-[3-(1-adamantyl)-4-hexyloxyphenyl]-2-naphthoic acid,

[0059] 6-[3-(1-adamantyl)-4-hexyloxyphenyl]-2-naphthoic acid,

[0060] the methyl ester of 6-[3-(1-adamantyl)-4-methoxyphenyl]-4-acetoxy-1-methyl-2-naphthoic acid,

[0061] 6-[3-(1-adamantyl)-4-methoxyphenyl]-4-hydroxy-1-methyl-2-naphthoic acid,

[0062] the methyl ester of 6-[3-(1-adamantyl)-4-methoxyphenyl]-4-hydroxy-1-methyl-2-naphthoic acid,

[0063] the methyl ester of 6-[3-(1-adamantyl)-4-methoxyphenyl)-1-methyl-2-naphthoic acid,

[0064] 6-[3-(1-adamantyl)-4-methoxyphenyl]-1-methyl-2-naphthoic acid,

[0065] 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthalenemethanol,

[0066] the ethyl amide of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid,

[0067] the morpholide of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid,

[0068] the methyl ester of 6-[3-(tert-butyl)-4-methoxyphenyl]-2-naphthoic acid,

[0069] 6-[3-(tert-butyl)-4-methoxyphenyl]-2-naphthoic acid,

[0070] the methyl ester of 6-[3-(1,1-dimethyldecyl)-4-methoxyphenyl]-2-naphthoic acid,

[0071] 6-[3-(1,1-dimethyldecyl)-4-methoxyphenyl]-2-naphthoic acid.

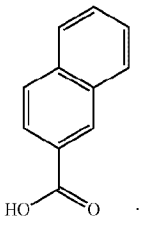
[0072] The present invention thus features compositions comprising, formulated into the same physiologically acceptable medium:

[0073] at least one naphthoic acid compound,

[0074] benzoyl peroxide, and

[0075] at least one gelling agent of the family of the carrageenans.

[0076] The naphthoic acid is a compound of formula:



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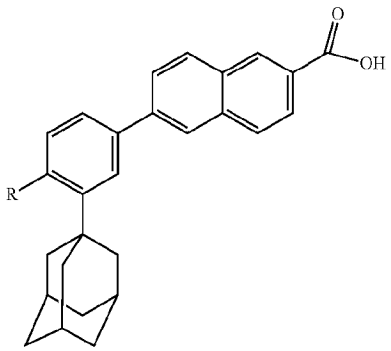
[0077] The term "naphthoic acid compound" means the compounds of formula (I):

(I)



wherein

[0078] R is a hydrogen atom, a hydroxyl radical, a branched or unbranched alkyl radical having from 1 to 4 carbon atoms, an alkoxy radical having from 1 to 10 carbon atoms or a cycloaliphatic radical which is substituted or unsubstituted.

[0079] The term "linear or branched alkyl radical having from 1 to 4 carbon atoms" means the methyl, ethyl, propyl and butyl radicals.

[0080] The term "alkoxy radical having from 1 to 10 carbon atoms" is preferably understood to mean the methoxy, ethoxy, propoxy, butoxy, hexyloxy and decyloxy radicals.

[0081] The term "cycloaliphatic radical" is preferably understood to mean mono- or polycyclic radicals, such as the 1-methylcyclohexyl radical or the 1-adamantyl radical.

[0082] The selection will advantageously be made, among the naphthoic acid compounds suitable for inclusion in the compositions according to the invention, of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid (adapalene), 6-[3-(1-adamantyl)-4-hydroxyphenyl]-2-naphthoic acid, 6-[3-(1-adamantyl)-4-decyloxyphenyl]-2-naphthoic acid and 6-[3-(1-adamantyl)-4-hexyloxyphenyl]-2-naphthoic acid.

[0083] The abovementioned naphthoic acid compounds are generally provided in a dispersed form in the composition according to the invention. Insoluble naphthoic acid compounds are thus homogeneously distributed in the composition according to the invention.

[0084] In particular, preference will be given to adapalene and its salts.

[0085] The term "salts of adapalene" means the salts formed with a pharmaceutically acceptable base, in particular inorganic bases, such as sodium hydroxide, potassium hydroxide and aqueous ammonia, or organic bases, such as lysine, arginine or N-methylglucamine.

[0086] The term "salts of adapalene" is also understood to mean the salts formed with fatty amines, such as dioctylamine and stearylamine.

[0087] Other retinoids can be selected from tretinoin, isotretinoin, retinoic acid, retinal, retinol or retinyl palmitate, in particular those described in the following patents or patent applications: U.S. Pat. Nos. 4,666,941, 4,581,380, EP-0210929, EP-0232199, EP-0260162, EP-0292348, EP-0325540, EP-0359621, EP-0409728, EP-0409740, EP-0552282, EP-0584191, EP-0514264, EP-0514269, EP-0661260, EP-0661258, EP-0658553, EP-0679628,

EP-0679631, EP-0679630, EP-0708100, EP-0709382, EP-0722928, EP-0728739, EP-0732328, EP-0740937, EP-0776885, EP-0776881, EP-0823903, EP-0832057, EP-0832081, EP-0816352, EP-0826657, EP-0874626, EP-0934295, EP-0915823, EP-0882033, EP-0850909, EP-0879814, EP-0952974, EP-0905118, EP-0947496, WO98/56783, WO99/10322, WO99/50239 and WO99/65872.

[0088] Of course, the amount of the two active agents, benzoyl peroxide and retinoid, in the composition according to the invention would depend on the combination selected and thus in particular on the retinoid under consideration and on the quality of the desired treatment.

[0089] The preferred concentrations of retinoid are from 0.0001 to 20% by weight, with respect to the total weight of the composition.

[0090] In the compositions according to the invention, the naphthoic acid compounds are included at concentrations of less than or equal to 10% by weight, with respect to the total weight of the composition, and preferably from 0.001 to 10% by weight, with respect to the total weight of the composition, and preferably from 0.01 to 5% by weight, more preferably from 0.05 to 2% by weight and most preferably from 0.1 to 0.3% by weight, with respect to the total weight of the composition.

[0091] Throughout the present text, unless otherwise specified, it is understood that, when ranges of concentrations are given, they include the upper and lower limits of the said range.

[0092] Advantageously, the naphthoic acid compound formulated in the compositions according to the invention is 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid (adapalene). Preferably, in the case of adapalene, the compositions according to the invention comprise from 0.001 to 5% by weight and advantageously from 0.01 to 1% by weight of adapalene, with respect to the total weight of the composition, preferentially from 0.01 to 0.5% by weight, preferably from 0.1 to 0.4% by weight of adapalene, more preferably still 0.1% by weight or 0.3% by weight of adapalene.

[0093] In the compositions according to the invention, benzoyl peroxide is formulated at concentrations ranging from 0.5 to 10% by weight, more particularly from 1 to 7% by weight and more preferably still from 2.5 to 5% by weight, with respect to the total weight of the composition.

[0094] The benzoyl peroxide can just as easily be formulated in the free form or else in an encapsulated form, in a form adsorbed on or absorbed in any porous support.

[0095] It can, for example, be benzoyl peroxide encapsulated in a polymeric system composed of porous microspheres, such as, for example, microsponges marketed under the trademark Microsponges P009A Benzoyl Peroxide by Cardinal Healthcare.

[0096] To provide an order of magnitude, the compositions according to the invention advantageously comprise from 0.0001 and 20% by weight of benzoyl peroxide and from 0.0001 to 20% by weight of retinoid, with respect to the total weight of the composition, and preferably from 0.025 to 10% by weight of benzoyl peroxide and from 0.001 to 10% by weight of retinoid respectively, with respect to the total weight of the composition.

[0097] For example, in the compositions for the treatment of acne, the benzoyl peroxide is preferably formulated at concentrations ranging from 0.5 to 10% by weight and more particularly from 1.0 to 5% by weight, with respect to the total weight of the composition; for its part, the retinoid is formulated in this type of composition at concentrations generally ranging from 0.05 to 1% by weight, with respect to the total weight of the composition.

[0098] Advantageously, the particle size of the retinoid and of the benzoyl peroxide is such that at least 80% by number of the particles and preferably at least 90% by number of the particles have a diameter of less than 25 μm and at least 99% by number of the particles have a diameter of less than 100 μm.

[0099] The compositions according to the invention additionally comprise at least one gelling agent of the family of the carrageenans.

[0100] Carrageenans are polysaccharides constituting the cell walls of various red algae (Rhodophyceae) belonging to the Gigartinacae, Hypneaceae, Furcellariaceae and Polyideaceae families. They are generally obtained by aqueous extraction starting from natural strains of the said algae. They comprise long anionic polyelectrolyte galactane chains. These linear polymers, formed of disaccharide units, are composed of two D-galactopyranose units alternatively bonded via α and β bonds. These are highly sulfated (20-50%) polysaccharides and the α-D-galactopyranosyl residues can be in the 3',6'-anhydro form.

[0101] Initially, the carrageenans were subdivided into two families according to their solubility in KCl. The fractions soluble in KCl were denoted by the prefixes "kappa" while the "lambda" terms were reserved for the insoluble fractions. Later, the classifications were based on the number and the position of sulfate groups and on the presence of the 3',6'-anhydro bridge on the β-D-galactopyranosyl residues. This resulted in the four main families: κ, λ, β, ω and ι.

[0102] Carrageenans are essentially composed of potassium, sodium, magnesium, triethanolamine and/or calcium salts and sulfate esters of polysaccharides.

[0103] Thus, carrageenans are capable of conferring a viscosity on the composition sufficient to keep the retinoid and the benzoyl peroxide in suspension, even under the influence in particular of a variation in pH due to the release of benzoic acid by the benzoyl peroxide. For the kappa and iota forms, the contribution of potassium ions or of calcium ions is necessary to ensure gelling and thus to have an impact on the viscosity. This is because the gelling mechanism exhibits two major stages (Selim Kara, "*Photon transmission study on swelling of kappa-carrageenan gels prepared in various concentrations", International Journal of Biological Macromolecules,* 33 (2003), 235-243) (Tommasina Coviello, "*Polysaccharide hydrogels for modified release formulations", Journal of Controlled Release,* 119 (2007), 5-24):

[0104] the formation of helices;

[0105] the action of the cations causes the helices to come together and brings about the formation of aggregates.

[0106] The gelling mechanism thus takes place.

[0107] The amount of carrageenan can vary to a large extent and depends in particular on the viscosity desired, on the carrageenan used and optionally on the other gelling agents present in the composition. To provide an order of magnitude, the carrageenan can be formulated at concentrations of 0.1 to 20% by weight, with respect to the total weight of the composition, and more preferably from 0.1 to 10% to preferably from 0.5 to 2%, in particular 0.5%, 1% to 2%.

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