



(51) International Patent Classification:

A61K 9/00 (2006.01) *A61K 31/327* (2006.01)
A61K 31/192 (2006.01) *A61P 17/10* (2006.01)

(21) International Application Number:

PCT/EP2015/066331

(22) International Filing Date:

16 July 2015 (16.07.2015)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

62/029,043 25 July 2014 (25.07.2014) US

(71) Applicant: **GALDERMA RESEARCH & DEVELOPMENT** [FR/FR]; 2400 Route des Colles Les Templiers, 06410 Biot (FR).

(72) Inventors: **LEONI, Matthew James**; 1 Rockhill Dr., Hampton, New Jersey 08827 (US). **GRAEBER, Michael**; 30103 Palm Court, Lawrenceville, New Jersey 08648 (US). **MANNA, Vasant**; 40 Colleen Circle, Ewing, New Jersey 08638 (US).

(74) Agent: **CASALONGA**; Casalonga & Associés, 8 Avenue Percier, 75008 Paris (FR).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AO, AT, AU, AZ, BA, BB, BG, BH, BN, BR, BW, BY, BZ, CA, CH, CL, CN, CO, CR, CU, CZ, DE, DK, DM, DO, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GT, HN, HR, HU, ID, IL, IN, IR, IS, JP, KE, KG, KN, KP, KR, KZ, LA, LC, LK, LR, LS, LU, LY, MA, MD, ME, MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO, NZ, OM, PA, PE, PG, PH, PL, PT, QA, RO, RS, RU, RW, SA, SC, SD, SE, SG, SK, SL, SM, ST, SV, SY, TH, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, ZA, ZM, ZW.

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LR, LS, MW, MZ, NA, RW, SD, SL, ST, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, RU, TJ, TM), European (AL, AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HR, HU, IE, IS, IT, LT, LU, LV, MC, MK, MT, NL, NO, PL, PT, RO, RS, SE, SI, SK, SM, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, KM, ML, MR, NE, SN, TD, TG).

Published:

— with international search report (Art. 21(3))

(54) Title: COMBINATION OF ADAPALENE AND BENZOYL PEROXIDE FOR THE TREATMENT OF SEVERE ACNE

(57) Abstract: The present invention concerns a pharmaceutical composition comprising 0.3% by weight of adapalene or a pharmaceutically acceptable salt thereof and 2.5% by weight of benzoyl peroxide, as active ingredients, for its use by topical administration in the treatment of inflammatory acne lesions. The present invention further concerns regimen for the therapeutic treatment of acne lesions in subjects afflicted with severe acne. The regimen includes topically applying to a subject's skin, as active ingredients, 0.3% by weight adapalene and 2.5% by weight benzoyl peroxide, combined in a single formula that delivers the active ingredients together. The single formula can for example be applied once or twice daily for a period of 8 to 12 weeks.



WO 2016/012352 A1