(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
20 January 2005 (20.01.2005)

PCT

(10) International Publication Number
WO 2005/004920 A1

(51) International Patent Classification[7]: A61K 47/26, 47/36, 47/38, 47/40, 31/7048

(21) International Application Number: PCT/IB2004/001610

(22) International Filing Date: 12 May 2004 (12.05.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

60/487,837	15 July 2003 (15.07.2003)	US
10/636,013	6 August 2003 (06.08.2003)	US

(71) Applicant *(for all designated States except US)*: **PFIZER PRODUCTS INC.** [US/US]; Eastern Point Road, Groton, CT 06340 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **COLLIER, Steven, William** [US/US]; 6732 Manor Crest, Oakland, CA 94618 (US). **CURATOLO, William, John** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **JOHNSON, Barbara, Alice** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US). **MURPHY, Brendan, John** [US/US]; Pfizer Global Research and Development, Eastern Point Road, Groton, CT 06340 (US).

(74) Agents: **FULLER, Grover, F., Jr.** et al.; c/o SIMPSON, Alison, Urquhart-Dykes & Lord LLP, 30 Welbeck Street, London W1G 8ER (GB).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States *(unless otherwise indicated, for every kind of regional protection available)*: ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: STABLE NON-DIHYDRATE AZITHROMYCIN ORAL SUSPENSIONS

(57) Abstract: This invention relates to a powder for oral suspension, and an oral suspension made there from, which comprises non-dihydrate azithromycin and an azithromycin conversion stabilizing excipient, wherein said excipient reduces the conversion of the form of azithromycin, when placed in suspension, to another form of azithromycin. This invention further relates to a method for reducing the conversion of a form of non-dihydrate azithromycin, in an oral suspension, by adding a surface tension reducing excipient that reduces the surface tension of the aqueous vehicle. Furthermore, this invention relates to a method for reducing the conversion of a non-dihydrate azithromycin, in an unflavored oral suspension, by raising the viscosity of the oral suspension, and in a flavored oral suspension by lowering the viscosity of the oral suspension.

WO 2005/004920 A1