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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
13 February 2003 (13.02.2003)

PCT

(10) International Publication Number
WO 03/011283 A1

(51) International Patent Classification[7]: A61K 31/40, 31/44, A61P 9/00, 9/08, 9/10, 9/12, 9/14 // (A61K 31/40, 31:44)

(21) International Application Number: PCT/IB02/02988

(22) International Filing Date: 29 July 2002 (29.07.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/309,133 31 July 2001 (31.07.2001) US

(71) Applicant *(for all designated States except US)*: **WARNER-LAMBERT COMPANY** [US/US]; 201 Tabor Road, Morris Plains, NJ 07950 (US).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **ALANI, Laman** [US/US]; Pfizer Global Research and Development, Ann Arbor Laboratories, 2800 Plymouth Road, Ann Arbor, MI 48105 (US). **KHAN, Sadath, Ulla** [US/US]; Pfizer Global Research and Development, Ann Arbor Laboratories, 2800 Plymouth Road, Ann Arbor, MI 48105 (US). **MACNEIL, Thomas, Michael** [US/US]; Pfizer Global Research and Development, Ann Arbor Laboratories, 2800 Plymouth Road, Ann Arbor, MI 48105 (US). **MUHAMMAD, Nouman, Abdul-Hussain** [US/US]; Pfizer Global Research and Development, Ann Arbor Laboratories, 2800 Plymouth Road, Ann Arbor, MI 48105 (US).

(74) Agents: **LUMB, J., Trevor** et al.; c/o Simpson, Alison, Urquhart-Dykes & Lord, 30 Welbeck Street, London, W1G 8ER (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, 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, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZM, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (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.

WO 03/011283 A1

(54) Title: PHARMACEUTICAL COMPOSITIONS OF AMLODIPINE AND ATORVASTATIN

(57) Abstract: A pharmaceutical composition comprising two components: (a) one component comprising a granulation of atorvastatin or pharmaceutically acceptable salts thereof and a carrier including an alkalizing agent that forms a pH greater than 5; and (b) a second component comprising amlodipine or pharmaceutically acceptable salts thereof and a carrier excluding an alkalizing agent that forms a pH greater than 5, wherein the two components are combined to form a final composition for a solid dosage form is described as well as methods to prepare the compositions, kits for containing such compositions, and a method of treating angina pectoris, atherosclerosis, combined hypertension and hyperlipidemia and/or hypercholesterolemia, and symptoms of cardiac risk using a therapeutically effective amount of the pharmaceutical composition.