

CORRECTED VERSION

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
12 September 2008 (12.09.2008)

PCT

(10) International Publication Number
WO 2008/106901 A8

- (51) International Patent Classification:
A61K 31/40 (2006.01) A61K 9/28 (2006.01)
A61K 9/16 (2006.01)
- (21) International Application Number:
PCT/CZ2008/000024
- (22) International Filing Date:
3 March 2008 (03.03.2008)
- (25) Filing Language: Czech
- (26) Publication Language: English
- (30) Priority Data:
PV 2007-169 2 March 2007 (02.03.2007) CZ
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- (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, BR, BW, BY, BZ,
CA, CH, 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, IS, JP, KE, KG, KM, KN, KP, KR,
KZ, LA, LC, LK, LR, LS, LT, LU, LY, MA, MD, ME,
MG, MK, MN, MW, MX, MY, MZ, NA, NG, NI, NO,
NZ, OM, PG, PH, PL, PT, RO, RS, RU, SC, SD, SE, SG,
SK, SL, SM, SV, SY, 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, 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, HR, HU, IE, IS, IT, LT, LU, LV,
MC, MT, NL, NO, PL, PT, RO, SE, SI, SK, TR), OAPI
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

Declarations under Rule 4.17:

— as to applicant's entitlement to apply for and be granted
a patent (Rule 4.17(ii))

Published:

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

(48) Date of publication of this corrected version:

1 April 2010

(15) Information about Correction:

see Notice of 1 April 2010

(54) Title: A PHARMACEUTICAL COMPOSITION WITH ATORVASTATIN ACTIVE INGREDIENT

(57) Abstract: A pharmaceutical composition containing the active substance atorvastatin in the form of oblong-shaped tablets with the length of 5 to 22 mm and the width of 2 to 11 mm or round tablets with the diameter of 3 to 16 mm, the core of which is constituted of compressed granulate and contains: i. Atorvastatin and/or at least one physiologically acceptable salt thereof in the quantity of 5 to 10% by weight, related to pure atorvastatin; ii. An organic or inorganic base selected from meglumine or an alkali metal hydroxide or their combination in the quantity of 0.01 to 7% by weight; iii. A pharmaceutically acceptable filler in the quantity of 20 to 90% by weight; iv. A disintegrant in the quantity of 0.5 to 50% by weight; provided with a coat that makes up 1 to 15% of the weight of the core, the selected base being uniformly distributed in the tablet core by means of spraying the same on the solid mixture in the granule production process. The composition can be obtained by a procedure consisting of the following steps: i. Mixing a mixture of atorvastatin, a filler and a disintegrant; ii. Dissolving a base in a mixture of water and a C₁ to C₃ alcohol in the quantity of 10 : 90 to 90 : 10 (water/alcohol, by weight); iii. Spraying the dry mixture with the base solution either in a masticating or fluidizing device; iv. Adapting the size of particles of the resulting granulate, preferably by re-sieving to the granule size of 0.1 to 1.5 mm; v. Adding other extragranular components to the granulate that will further improve its ability to be compressed into tablets; vi. Compressing the mixture; and vii. Applying a coat on the compressed tablets.



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