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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
15 November 2007 (15.11.2007)

PCT

(10) International Publication Number
WO 2007/129961 A1

(51) International Patent Classification:
A61K 9/08 (2006.01) *A61K 31/4439* (2006.01)
A61L 2/08 (2006.01) *A61K 31/444* (2006.01)
A61K 31/4184 (2006.01) *A61P 1/04* (2006.01)

(21) International Application Number:
PCT/SE2007/000440

(22) International Filing Date: 7 May 2007 (07.05.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/799,058 9 May 2006 (09.05.2006) US

(71) Applicant *(for all designated States except US)*: **ASTRAZENECA AB** [SE/SE]; S-151 85 Södertälje (SE).

(72) Inventors; and
(75) Inventors/Applicants *(for US only)*: **BRÜLLS, Mikael** [SE/SE]; AstraZeneca R & D Mölndal, S-431 83 Mölndal (SE). **LAURILA, Johanna** [SE/SE]; AstraZeneca R & D Mölndal, S-431 83 Mölndal (SE).

(74) Agent: **ASTRAZENECA AB**; Global Intellectual Property, S-151 85 Södertälje (SE).

(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BH, 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, 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, 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, HU, IE, IS, IT, LT, LU, LV, MC, MT, 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.

WO 2007/129961 A1

(54) **Title:** PARENTERAL FORMULATION COMPRISING PROTON PUMP INHIBITOR STERILIZED IN ITS FINAL CONTAINER BY IONIZING RADIATION

(57) **Abstract:** The present invention relates to a stable sterilized parenteral formulation comprising an acid susceptible proton pump inhibitor. The formulation, a solid formulation comprising the acid susceptible proton pump inhibitor and optionally pharmaceutically acceptable excipients, has been sterilized in its final container by ionizing radiation. The container may consist of several compartments and separately contains a suitable solvent, which is sterilized, i.e. radiated, at the same time as the solid formulation. Alternatively, the suitable solvent is sterilized separately or aseptically manufactured. The solid formulation is dissolved in a suitable solvent before being administered to the patient, i.e. being prepared *ex tempore*. The present invention also relates to the prepared sterilized parenteral formulation, the stable solid formulation, processes for obtaining said parenteral formulation and the solid formulation as well as to the therapeutic uses thereof.