

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
18 December 2008 (18.12.2008)

PCT

(10) International Publication Number
WO 2008/153582 A1

(51) International Patent Classification:

A61K 9/00 (2006.01) A61K 31/215 (2006.01)
A61K 47/12 (2006.01) A61K 31/24 (2006.01)

(21) International Application Number:

PCT/US2007/074325

(22) International Filing Date: 25 July 2007 (25.07.2007)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

11/752,037 22 May 2007 (22.05.2007) US

(71) Applicants (for all designated States except US): **BAXTER INTERNATIONAL INC.** [US/US]; One Baxter Parkway DF2-2W, Deerfield, Illinois 60015 (US). **BAXTER HEALTHCARE S.A.** [CH/CH]; Hertistrasse 2, CH-8304 Wallisellen (CH).

(72) Inventors; and

(75) Inventors/Applicants (for US only): **TIWARI, Deepak** [US/US]; 53 Vones Lane, Raritan, New Jersey 08869 (US). **O'WOO, George** [US/US]; 208 Harding Avenue, North Plainfield, New Jersey 07063 (US). **NAYAK, Rekha** [IN/US]; 13 Arlene Court, Monmouth Junction, NJ 08852 (US). **BURHOP, Kenneth E** [US/US]; 11009 Sandpiper Court, Spring Grove, Illinois 60081 (US).

(74) Agents: **MAYO, Michael C** et al.; Baxter International INC., One Baxter Parkway DF2-2W, Deerfield, Illinois 60015 (US).

(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, 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, 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).

Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii))
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii))

Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

(54) Title: CONCENTRATE ESMOLOL

(57) Abstract: A concentrate esmolol formulation is provided that is safer than current concentrate (e.g., 250 mg/ml) esmolol compositions. The concentrate esmolol formulation can include from about 40-60 mg/ml of esmolol hydrochloride. The concentrate esmolol composition allows a practitioner the flexibility of choosing a bolus volume for direct injection to a patient or, optionally, to use the composition to make a customized, diluted composition of esmolol. Methods of the present invention provide for the reduction of potential adverse health consequences resulting in the improper dosing of prior art concentrate compositions of esmolol. Also, a medical product is provided that includes a concentrate esmolol housed in a container, and a package housing the container and instructions.



WO 2008/153582 A1