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

(19) World Intellectual Property Organization
International Bureau

162162

(43) International publication date
3 October 2002 (03.10.2002)

PCT

(10) International publication number
WO 02/076495 A1

(51) International patent classification[7]: A61K 38/28, 47/00

(21) International application number: PCT/EP02/02625

(22) International filing date: 9 March 2002 (09.03.2002)

(25) Language of filing: German

(26) Language of publication: German

(30) Data relating to the priority:
10114178.5 23 March 2001 (23.03.2001) DE

(71) Applicant *(for all designated States except US)*: AVENTIS PHARMA DEUTSCHLAND GMBH [DE/DE]; Brüningstrasse 50, 65929 Frankfurt (DE).

(72) Inventor: BODERKE, Peter; Johannesallee 16, 65929 Frankfurt (DE).

(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, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, 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, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI Patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
- *With the International Search Report.*
- *Before expiry of the period provided for amending the claims, will be republished if such amendments are received.*

For an explanation of the two-letter codes and the other abbreviations, reference is made to the explanations ("Guidance Notes on Codes and Abbreviations") at the beginning of each regular edition of the PCT Gazette.

As printed

(54) Title: INSULIN PREPARATIONS, WHICH DO NOT CONTAIN ANY ZINC OR ONLY A SMALL QUANTITY OF ZINC AND WHICH HAVE AN IMPROVED STABILITY

(54) Bezeichnung: ZINKFREIE UND ZINKARME INSULINZUBEREITUNGEN MIT VERBESSERTER STABILITAT

(57) Abstract: The invention relates to a pharmaceutical formulation containing: a polypeptide selected from a group containing insulin, an insulin metabolite, an insulin analog, an insulin derivative or combinations thereof; a surfactant or combinations of several surfactants; optionally, a preservative or combinations of several preservatives, and, optionally, an isotonizing agent, buffers or additional adjuvants or combinations thereof, whereby the pharmaceutical formulation does not contain any zinc or only a small quantity of zinc. The invention also relates to the production of insulin preparations of the aforementioned type

(57) Zusammenfassung: Die Erfindung betrifft eine pharmazeutische Formulierung enthaltend ein Polypeptid ausgewählt aus einer Gruppe enthaltend Insulin, einen Insulinmetaboliten, ein Insulinanalogon, ein Insulinderivat oder Kombinationen davon, ein Tensid oder Kombinationen mehrerer Tenside, optional ein Konservierungsmittel oder Kombinationen mehrerer Konservierungsmittel; und optional ein Isotonisierungsmittel, Puffer oder weitere Hilfsstoffe oder Kombinationen davon, wobei die pharmazeutische Formulierung frei von oder arm an Zink ist und die Herstellung solcher Insulinzubereitungen

WO 02/076495 A1

G00002