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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
3 November 2005 (03.11.2005)

PCT

(10) International Publication Number
WO 2005/102271 A3

(51) International Patent Classification:
A61K 9/20 (2006.01)

(21) International Application Number:
PCT/EP2005/004400

(22) International Filing Date: 21 April 2005 (21.04.2005)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:

0401031-0	22 April 2004 (22.04.2004)	SE
60/564,205	22 April 2004 (22.04.2004)	US

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(81) Designated States *(unless otherwise indicated, for every kind of national protection available)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, 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, HR, HU, ID, IL, IN, IS, JP, KE, KG, KM, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SM, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, 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, MC, 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*

(88) Date of publication of the international search report:
3 August 2006

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.

(54) Title: PHARMACEUTICAL COMPOSITIONS FOR GLUCOCORTICOID REPLACEMENT THERAPY

(57) Abstract: The invention relates to glucocorticoid replacement therapy and provides pharmaceutical compositions and kits designed to deliver one or more glucocorticoids to a subject in need thereof in a manner that results in serum levels of the glucocorticoid that essentially mimic that of a healthy subject for a clinically relevant period of time. The pharmaceutical composition comprises one or more glucocorticoids, wherein a first part of one or more glucocorticoids is substantially immediately released and a second part of one or more glucocorticoids is released over an extended period of time of at least about 8 hours, and the amount of the one or more glucocorticoids of the first part, expressed as hydrocortisone equivalents, is in a range of from about 15 to about 50% of the total hydrocortisone equivalents. The invention also relates to a kit comprising a first and a second component, the first component designed to release one or more glucocorticoids substantially immediately and the second component is designed to release one or more glucocorticoids over an extended period of time of at least 8 hours. The invention also relates to a method for treating diseases requiring glucocorticoid treatment such as in subjects having a glucocorticoid deficiency disorder. In another aspect the invention relates to the use of a first and a second amount of one or more glucocorticoids for the preparation of a pharmaceutical composition or kit for the treatment of a glucocorticoid deficiency disorder.

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