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

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 February 2003 (27.02.2003)

PCT

(10) International Publication Number
WO 03/015690 A3

(51) International Patent Classification[7]: A61K 9/20

(21) International Application Number: PCT/IL02/00662

(22) International Filing Date: 12 August 2002 (12.08.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
144900 14 August 2001 (14.08.2001) IL

(71) Applicant *(for all designated States except US)*: **NEURIM PHARMACEUTICALS LTD. (1991) LTD.** [IL/IL]; 8 Hanechoshet Street, 69710 Tel Aviv (IL).

(72) Inventor; and
(75) Inventor/Applicant *(for US only)*: **ZISAPEL, Nava** [IL/IL]; 23 Kisufim Street, 69355 Tel Aviv (IL).

(74) Agent: **JEREMY M. BEN-DAVID & CO. LTD.**; Har Hotzvim Hi-Tech Park, P.O. Box 45087, 91450 Jerusalem (IL).

(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, OM, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, 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, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK, TR), OAPI patent (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:
25 September 2003

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 03/015690 A3

(54) Title: METHOD FOR TREATING PRIMARY INSOMNIA

(57) Abstract: The invention relates to a medicament, for treating and improving the restorative quality of sleep, in a patient suffering from primary insomnia, which comprises at least one compound selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists, in an effective amount within the range of 0.0025 to 50 mg, and optionally one or more other therapeutically active agents.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IL02/00662

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 9/20
US CL : 424/464

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/464

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,498,423 A (ZISAPEL) 12 March 1996. See entire document.	1-10
Y, P	US 6,423,738 B1 (LEWY et al.) 23 July 2002. See entire document.	1-10

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
23 January 2003 (23.01.2003)

Date of mailing of the international search report
21 FEB 2003

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231
Facsimile No. (703)305-3230

Authorized officer
Liliana Di Nola-Baron
Telephone No. 308-1234/ 1235

Form PCT/ISA/210 (second sheet) (July 1998)