



(12) Translation of
European patent specification

(11) NO/EP 2931276 B1

NORWAY

(19) NO
(51) Int Cl.
A61K 31/445 (2006.01)
A61K 31/495 (2006.01)
A61P 25/00 (2006.01)
A61P 25/16 (2006.01)
A61P 25/24 (2006.01)
A61P 25/28 (2006.01)

Norwegian Industrial Property Office

| | | |
|------|--|---|
| (21) | Translation Published | 2018.05.28 |
| (80) | Date of The European Patent Office Publication of the Granted Patent | 2018.02.21 |
| (86) | European Application Nr. | 13818702.6 |
| (86) | European Filing Date | 2013.12.12 |
| (87) | The European Application's Publication Date | 2015.10.21 |
| (30) | Priority | 2012.12.13, US, 201261736799 P |
| (84) | Designated Contracting States: | AL ; AT ; BE ; BG ; CH ; CY ; CZ ; DE ; DK ; EE ; ES ; FI ; FR ; GB ; GR ; HR ; HU ; IE ; IS ; IT ; LI ; LT ; LU ; LV ; MC ; MK ; MT ; NL ; NO ; PL ; PT ; RO ; RS ; SE ; SI ; SK ; SM ; TR |
| | Designated Extension States: | BA ME |
| (73) | Proprietor | H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, DK-Danmark |
| (72) | Inventor | MORILLO, Connie, Sanchez, 17 Deborah Lane, West Milford, New Jersey 07480, US-USA |
| (74) | Agent or Attorney | BRYN AARFLOT AS, Stortingsgata 8, 0161 OSLO, Norge |

(54) Title **COMPOSITIONS COMPRISING VORTIOXETINE AND DONEPEZIL**

(56) References Cited:
WO-A1-2009/062517, US-A1- 2008 032 965, CACHARD-CHASTEL ET AL: "Prucalopride and donepezil act synergistically to reverse scopolamine-induced memory deficit in C57Bl/6j mice", BEHAVIOURAL BRAIN RESEARCH, ELSEVIER, AMSTERDAM, NL, vol. 187, no. 2, 18 October 2007 (2007-10-18), pages 455-461, XP022419975, ISSN: 0166-4328, DOI: 10.1016/J.BBR.2007.10.008, RIVEROL M ET AL: "Efficacy and tolerability of a combination treatment of memantine and donepezil for alzheimer's disease: A literature review evidence", EUROPEAN NEUROLOGICAL JOURNAL 2011 SAN LUCAS MEDICAL LTD GBR,, vol. 3, no. 1, January 2011 (2011-01), pages 15-19, XP002718911, ISSN: 2041-8000, DE BRUIN N M W J ET AL: "Two novel 5-HT6 receptor antagonists ameliorate scopolamine-induced memory deficits in the object recognition and object location tasks in Wistar rats.", NEUROBIOLOGY OF LEARNING AND MEMORY SEP 2011, vol. 96, no. 2, September 2011 (2011-09), pages 392-

402, XP055100651, ISSN: 1095-9564, DOI: 10.1016/j.nlm.2011.06.015, SELTZER B: "Donepezil: An update", EXPERT OPINION ON PHARMACOTHERAPY, ASHLEY PUBLICATIONS LTD, LONDON, UK, vol. 8, no. 7, May 2007 (2007-05), pages 1011-1023, XP009175600, ISSN: 1465-6566, DOI: 10.1517/14656566.8.7.1011, ADELL ALBERT: "Lu-AA21004, a multimodal serotonergic agent, for the potential treatment of depression and anxiety.", IDRUGS : THE INVESTIGATIONAL DRUGS JOURNAL DEC 2010, vol. 13, no. 12, December 2010 (2010-12), pages 900-910, XP009176021, ISSN: 2040-3410, FRERET THOMAS ET AL: "Synergistic effect of acetylcholinesterase inhibition (donepezil) and 5-HT(4) receptor activation (RS67333) on object recognition in mice.", BEHAVIOURAL BRAIN RESEARCH 21 APR 2012, vol. 230, no. 1, 21 April 2012 (2012-04-21), pages 304-308, XP055100641, ISSN: 1872-7549, DOI: 10.1016/j.bbr.2012.02.012

Enclosed is a translation of the patent claims in Norwegian. Please note that as per the Norwegian Patents Acts, section 66i the patent will receive protection in Norway only as far as there is agreement between the translation and the language of the application/patent granted at the EPO. In matters concerning the validity of the patent, language of the application/patent granted at the EPO will be used as the basis for the decision. The patent documents published by the EPO are available through Espacenet (<http://worldwide.espacenet.com>) or via the search engine on our website here: <https://search.patentstyret.no/>

Patentkrav

1. Farmasøytisk sammensetning omfattende vortioksetin og donepezil sammen med en farmasøytisk akseptabel eksipiens.
5
2. Sammensetning ifølge krav 1 omfattende 5-25 mg donepezil.
3. Sammensetning ifølge krav 1 eller 2 omfattende 5-20 mg vortioksetin.
- 10 4. Vortioksetin og donepezil til anvendelse i en fremgangsmåte for behandling av en sykdom valgt fra kognitiv dysfunksjon; demens ved Alzheimers sykdom; vaskulær demens; demens ved Picks sykdom; demens ved Creutzfeldt-Jakobs sykdom; demens ved Huntingtons sykdom; demens ved Parkinsons sykdom; demens ved HIV (humant immunsviktivirus); demens hos misbrukere (alkohol eller narkotika); MCI (mild kognitiv svekkelse); kognitiv dysfunksjon forbundet med depresjon; og kognitiv
15 kognitiv dysfunksjon forbundet med schizofreni.
5. Vortioksetin og donepezil til anvendelse ifølge krav 4, hvor nevnte donepezil er mellom 5 og 25 mg donepezil.
20
6. Vortioksetin og donepezil til anvendelse ifølge krav 4 eller 5, hvor nevnte vortioksetin er mellom 5 og 20 mg vortioksetin.