



(12) Translation of
European patent specification

(11) NO/EP 3710058 B1

NORWAY

(19) NO

(51) Int Cl.

A61K 31/05 (2006.01)

A61K 31/352 (2006.01)

A61K 36/185 (2006.01)

A61K 45/06 (2006.01)

A61P 25/08 (2006.01)

Norwegian Industrial Property Office

(45)	Translation Published	2024.11.04
(80)	Date of The European Patent Office Publication of the Granted Patent	2024.10.09
(86)	European Application Nr.	18808075.8
(86)	European Filing Date	2018.11.15
(87)	The European Application's Publication Date	2020.09.23
(30)	Priority	2017.11.15, GB, 201718862
(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
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(54) Title **USE OF CANNABIDIOL IN ADDITION TO LAMOTRIGINE FOR THE TREATMENT OF SEIZURES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME**

(56) References

Cited:

US-A1- 2017 224 634

GB-A- 2 531 282

DEVINSKY ORRIN ET AL: "Cannabidiol in patients with treatment-resistant epilepsy: an open-label interventional trial", LANCET NEUROLOGY, LANCET PUBLISHING GROUP, LONDON, GB, vol. 15, no. 3, 24 December 2015 (2015-12-24), pages 270 - 278, XP029415431, ISSN: 1474-4422, DOI: 10.1016/S1474-4422(15)00379-8

ALICIA CICCONE: "Drop Seizure Frequency in Lennox-Gastaut Decreased With Cannabidiol", NEUROLOGY ADVISOR, 26 April 2017 (2017-04-26), pages 1 - 3, XP055544182, Retrieved from the Internet <URL:https://www.neurologyadvisor.com/aan-2017-coverage/aan-2017-cannabidiol-reduces-drop-seizures-in-lennox-gastaut-syndrome/article/652931/> [retrieved on 20190117]

WIRRELL E ET AL: "Cannabidiol (CBD) significantly reduces drop and total seizure frequency in lennox gastaut syndrome (LGS): Results of a dose ranging, multicenter, randomized, double blind, placebo controlled trial (GWPCARE3)", 1 October 2017 (2017-10-01), XP002788724, Retrieved from the Internet <URL:http://ir.gwpharm.com/static-files/d489e19a-7769-4dcb-97fc-60ed923b0a2d>

OSTENDORF ADAM ET AL: "Treatment-resistant Lennox-Gastaut syndrome: therapeutic trends, challenges and future directions", NEUROPSYCHIATRIC DISEASE AND TREATMENT, vol. Volume 13, 1 April 2017 (2017-04-01), pages 1131 - 1140, XP055939166, Retrieved from the Internet <URL:https://www.dovepress.com/getfile.php?fileID=36134> [retrieved on 20220706], DOI: 10.2147/NDT.S115996

O DEVINSKY ET AL: "Efficacy and safety of Epidiolex (cannabidiol) in children and young adults with treatment-resistant epilepsy: Initial data from expanded access program", 1 January 2015 (2015-01-01), XP055553292, Retrieved from the Internet
<URL:https://www.aesnet.org/meetings_events/annual_meeting_abstracts/view/2414222>
[retrieved on 20190207]

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Patentkrav

1. Cannabidiol (CBD) for anvendelse i behandling av atoniske anfall assosiert med Lennox-Gastaut syndrom (LGS) **karakterisert ved at** pasienten med LGS anses å være en behandlingssvikt med lamotrigin; hvori CBD er i form av et svært rensset ekstrakt av cannabis
5 som omfatter minst 98 % (vekt/vekt) CBD eller er til stede som en syntetisk forbindelse.
2. Cannabidiol (CBD) for anvendelse ifølge krav 1, hvori det svært rensede ekstraktet omfatter mindre enn 0,15 % THC.
- 10 3. Cannabidiol (CBD) for anvendelse ifølge krav 1, hvori ekstraktet videre omfatter opptil 1 % CBDV.
4. Cannabidiol (CBD) for anvendelse ifølge et hvilket som helst av de foregående kravene, hvori dosen av CBD er under 50 mg/kg/dag.
- 15 5. Cannabidiol (CBD) for anvendelse ifølge et hvilket som helst av de foregående kravene, hvori dosen av CBD er større enn 20 mg/kg/dag.